

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Equipment Design Verification Report		
Report # TE0084016-EDVR	Iteration # 00	SAP # TE0084016QX	

EQUIPMENT DESIGN VERIFICATION REPORT
For the 2690 Front Panel PCB Functional Test Fixture (TE0084016)

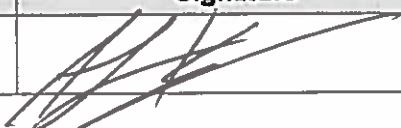
PREPARED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		18 Feb 2019

REVIEWED BY

Name	Role	Signature	Date
Ed Jackson	Principal Test Engineer		18 Feb 2019

APPROVED BY

Name	Role	Signature	Date
Andie Kopoyan	SI. Ops. Quality Engineer		18 Feb 2019

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

The "Reviewed By" signature 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 2690 Front Panel PCB Functional Test Fixture is a board fixture designed for use with the Waters Global Test System (TE82988) and is used to perform functional testing of the Alliance Front Panel PCB Assembly (P/N: 210000384). During the test the UUT is connected to the fixture and the test program on the GTS (TE82988) is launched. The automated test includes UUT power, CPU bus, keypad I/O, contrast control, backlight control, VRAM, and LCD output. Upon completion a test record is automatically generated and saved to the SigmaQuest Data Archive. This verification will demonstrate that the fixture is capable of verifying both the critical to quality requirements of the product under test and the functional performance to the equipment requirements.

2.0 Scope of Report

This Equipment Design Verification Report details the verification activities undertaken for the 2690 Front Panel PCB Functional Test Fixture (TE0084016) based on the requirements of the TE0084016-EDV_Iteration 01 Equipment Design Verification Protocol, which can be found at TE0084016QA in SAP.

This Equipment Design Verification Report defines the documents used to verify the 2690 Front Panel PCB Functional Test Fixture (TE0084016).

3.0 Summary of Results - Statement of Fitness for Intended Use

The 2690 Front Panel PCB Functional Test Fixture was tested in accordance with the TE0084016-EDV_Iteration 01. All required Test Scripts were performed and all objective evidence requirements have been met as defined by TE0084016-28JAN2019-VAF, which can be found at TE0084016QX in SAP.

Waters now has the necessary documentation in place to ensure that the 2690 Front Panel PCB Functional Test Fixture complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Verification Report, the 2690 Front Panel PCB Functional Test Fixture (TE0084016) can be considered fully verified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
Cal/PM	Calibration/Preventive Maintenance
cGMP	Current Good Manufacturing Practice
CPU	Central Processing Unit
EDV	Equipment Design Verification
EDVR	Equipment Design Verification Report
GTS	Global Test System
LCD	Liquid Crystal Display
OESR	Operations Engineering Service Request
OFI	Opportunity for Improvement
PCB	Printed Circuit Board
SAP	Enterprise Resource Planning Software
TSP	Test Specification and Procedure

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Term	Explanation
UUT	Unit Under Test
VAF	Validation Assessment Form

5.0 Training

The executor of this verification is the author of TE0084016-EDV_Iteration 01 and is considered trained to the protocol. The executor of this verification has been trained to the Waters GTS Operation TSP 735002109 Rev. A, Ver. 00. The training record is provided as Attachment 7.1.

6.0 Verification Results

6.1 Test Script EDV-01: Specification and Functional Verification was performed according to TE0084016-EDV_Iteration 01. The completed Test Script Data Sheet is provided as Attachment 7.2.

6.1.1 It was verified that TE0084016SF Version 0.1 was in use. Refer to the "TE0084016SF VER:0.1" line item printed on the test record provided as Attachment 7.3.

6.1.2 It was verified that testing a known good 2690 Front Panel PCB Assembly (P/N: 210000384, S/N: 270716063M) resulted in the system identifying the unit as passing. This test was performed using the 2690 Front Panel PCB Functional Test Fixture (TE0084016) on the GTS platform (TE82988-1). The passing test record as printed from the SigmaQuest Data Archive is provided as Attachment 7.3.

OESR #182960 has been submitted to correct typographical errors and add units to the test record. Note that the product field in the Test Record Header was manually filled in with "N/A" since the GTS platform (TE82988) does not report that value. The product field is generated by the SigmaQuest Data Archive. This is not caused by the test fixture TE0084016 or the test sequence for P/N: 210000384. This record is not printed as part of the production process.

The "Check+5VQuCurrent" test (4.2 on Test Script EDV-01: Specification and Functional Verification) verifies the voltage of the positive 5 V power supply by measuring current. The intent of this test is to verify that the power supply turns on and current cannot be measured when no voltage is present.

6.2 Test Script EDV-02: Fault Insertion Test was not performed according to TE0084016-EDV_Iteration 01 as specified in the Validation Assessment Form TE0084016-28JAN2019-VAF which can be found at TE0084016QX in SAP.

6.3 This table provides a summary of each test script as performed according to TE0084016-EDV_Iteration 01 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
EDV-01	Pass	Attachments 7.2 and 7.3	None

7.0 Attachments

7.1 Completed Executor Training Record

7.2 Completed Test Script EDV-01: Specification and Functional Verification

7.3 Passing Test Record for P/N: 210000384, S/N: 270716063M

8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the TE0084016-EDV_Iteration 01.

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9.0 References

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

Document Number	Document Title
730001835	Process Validation Procedure for Milford Site
730002845	Validation Report Template
730001833	Test Engineering Management Policy
735002109	Waters GTS Operation TSP
735004006	Waters GTS Preventative Maintenance and Calibration Procedure
710000384	2690 Front Panel PCB Schematic
810000384	2690 Front Panel PCB Performance Specification
TE0084016EQ	Equipment Design Documentation
TE0084016QA	Equipment Design Verification Protocol TE0084016-EDV_ Iteration 01
TE0084016QX	Validation Assessment Form TE0084016-28JAN2019-VAF

Title: individual Training Form

Document No: 730002657

Version No: 00

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Training Type:	Read and Understood		
Name:	Emma Pierce	Employee ID¹	034916
Date of Training	14 September 2018		
Comments:	N/A		

Document Number	Title	Rev. #
735002109	Waters GTS Operation TSP	00



Employee's Signature

Test Validation Engineer

Title

14 Sep 2018

Date

N/A - Self trained ELP 14 Sep 2018

Trainer's Signature

Title

Date

Document No.: TE00841216-EDVR
 Iteration No.: 0
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¹ Without preceding "90"

Protocol # TE0084016-EDV

Iteration # 01

SAP # TE0084016QA

Test Name: Specification and Functional Verification

Test Script No: EDV-01

Equipment Name: 2690 Front Panel PCB Functional Test Fixture

Equipment Number: TE0084016

Software Version: 0.1

Part Number: 210000384

Serial Number: 270716063 M

Purpose:

To ensure that obtained results that are within specification are measured/reported as such by the system.
To ensure that critical to quality specifications are properly implemented for test.

Test Execution:

Run the equipment until completion. Verify that all acceptance criteria listed below are met and documented on the Final Test Record.

Objective Evidence:

Completed Test Script Data Sheet

Copy of the Final Test record(s) for each UUT

Description Specification	Acceptance Criteria	Actual Result	Pass / Fail	Initial & Date
1. ValidSerialNumber				
1.1. ValidSerialNumber	Pass	PASS	PASS	EUP 13 Feb 2019
2. Measurement				
2.1. Measurement	Pass	PASS	PASS	EUP 13 Feb 2019
3. Vacuum				
3.1. FixtureID	38	38	PASS	EUP 13 Feb 2019
3.2. FixtureDown	Pass	PASS	PASS	EUP 13 Feb 2019
4. Test UUT Power				
4.1. Power Supply Status	Pass	PASS	PASS	EUP 13 Feb 2019
4.2. Check+5VQuCurrent	LSL: 0.03 USL: 0.07	0.046	PASS	EUP 13 Feb 2019
4.3. Test 3.3V Supply	LSL: 3.267 USL: 3.333	3.311	PASS	EUP 13 Feb 2019
5. Test CPU Bus				
5.1. Test Write_Read Operation	Pass	PASS	PASS	EUP 13 Feb 2019
5.2. TestDoorOpenSense	Pass	PASS	PASS	EUP 13 Feb 2019
5.3. TestDoorCloseSense	Pass	PASS	PASS	EUP 13 Feb 2019
6. Test Keypad I/O				
6.1. TestKeyPad	Pass	PASS	PASS	EUP 13 Feb 2019
7. Test Backlight Control				
7.1. TestLEDOutIsBright	LSL: 4.6 USL: 4.8	4.678	PASS	EUP 13 Feb 2019
7.2. TestLEDOutIsDim	LSL: 3.6 USL: 3.8	3.75	PASS	EUP 13 Feb 2019

Protocol # TE0084016-EDV

Iteration # 01

SAP # TE0084016QA

8. Test Contrast Control

8.1. CompletedSweep	Pass	Pass	Pass	ELP 13 Feb 2019
8.2. MaxContrastLevel	LSL: 16.2 USL: 16.7	16.465	Pass	ELP 13 Feb 2019
8.3. MinContrastLevel	LSL: 1.2 USL: 2.1	1.668	Pass	ELP 13 Feb 2019
8.4. UpLinearityError	LSL: -0.1 USL: 0.1	0.01	Pass	ELP 13 Feb 2019
8.5. DownLinearityError	LSL: -0.1 USL: 0.1	0.01	Pass	ELP 13 Feb 2019
8.6. AutoDownChange	LSL: -2.2 USL: -1	-1.578	Pass	ELP 13 Feb 2019
8.7. AutoUpChange	LSL: -2.2 USL: -1	-1.592	Pass	ELP 13 Feb 2019
8.8. MeasFinalContrastLevel	LSL: 11.5 USL: 12.5	11.91	Pass	ELP 13 Feb 2019

9. Test Vram

9.1. ValidateVramPg{1}	Pass	Pass	Pass	ELP 13 Feb 2019
9.2. ValidateVramPg{2}	Pass	Pass	Pass	ELP 13 Feb 2019
9.3. ValidateVramPg{3}	Pass	Pass	Pass	ELP 13 Feb 2019

10. Test LCDout

10.1. ClkFreq	Pass	Pass	Pass	ELP 13 Feb 2019
10.2. LCDoutPg{1}	Pass	Pass	Pass	ELP 13 Feb 2019
10.3. ClkFreq	Pass	Pass	Pass	ELP 13 Feb 2019
10.4. LCDoutPg{2}	Pass	Pass	Pass	ELP 13 Feb 2019
10.5. ClkFreq	Pass	Pass	Pass	ELP 13 Feb 2019
10.6. LCDoutPg{3}	Pass	Pass	Pass	ELP 13 Feb 2019

Comments:

N/A ELP 13 Feb 2019

Overall Test Conclusion:☒ Pass☐ Fail

Waters Corporation - Test Record

Part Number: 210000384Product: N/AOperator: administratorStart Time: 02/13/2019, 14:19:55Serial Number: 270716063MEnd Time: 02/13/2019, 14:21:20Test System: TE82988-1

Name	LSL	Measurement	USL	Unit	Outcome
ValidSerialNumber					PASS
Measurement		TE0084016SF VER:0.1			PASS
Vacuum					PASS
Vacuum On(Fixture Down)					DONE
FixtureID	NaN	38			PASS
FixtureDown					PASS
Test UUT Power					PASS
PowerSupplyStatus					PASS
Check+5VQuCurrent	0.03	0.046	0.07		PASS
Test 3.3V Supply	3.267	3.311	3.333		PASS
Test CPU Bus					PASS
ReadIrq/DoorStatusToClear					DONE
Test Write_Read Operation					PASS
SetDoorAsOpen					DONE
ReadIrq/DoorStaus					DONE
TestDoorOpenSense					PASS
SetDoorAsClosed					DONE
ReadIrq/DoorStaus					DONE
TestDoorCloseSense					PASS
Test Keypad I/O					PASS
TestKeyPad		Failed Key Codes:			PASS
Test Backlight Control					PASS
SetLEDLoadToBright					DONE
SetBacklightToBright					DONE
TestLEDOutIsBright	4.6	4.678	4.8		PASS
SetLEDLoadToDim					DONE
SetBacklightToDim					DONE
TestLEDOutIsDim	3.6	3.75	3.8		PASS
Test Contrast Control					PASS
CheckSweepQuality					DONE
CompletedSweep					PASS
MaxContrastLevel	16.2	16.465	16.7		PASS
MinContrastLevel	1.2	1.668	2.1		PASS
UpLinearityError	-0.1	0.01	0.1		PASS
DownLinearityError	-0.1	0.01	0.1		PASS
AutoDecContrastLevel					DONE
AutoDownChange	-2.2	-1.578	-1		PASS
AutoDecContrastLevel					DONE
AutoDownChange	-2.2	-1.592	-1		PASS
MeasFinalContrastLevel	11.5	11.91	12.5		PASS
Test Vram					PASS
InitVideoPage to 1					DONE
LoadVramPg{1}					DONE

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ReadVramPg{1}		DONE
ValidateVramPg{1}		PASS
LoadVramPg{2}		DONE
ReadVramPg{2}		DONE
ValidateVramPg{2}		PASS
LoadVramPg{3}		DONE
ReadVramPg{3}		DONE
ValidateVramPg{3}		PASS
Statement		SKIPPED
TestLCDOutput		PASS
SetVideoPage{1}		DONE
TestLCDDriverPg{1}		DONE
ClkFreq	1428571.43	PASS
LCDoutPg{1}		PASS
RecordAttempts		DONE
SetVideoPage{2}		DONE
TestLCDDriverPg{2}		DONE
ClkFreq	1428571.43	PASS
LCDoutPg{2}		PASS
RecordAttempts		DONE
SetVideoPage{3}		DONE
TestLCDDriverPg{3}		DONE
ClkFreq	1428571.43	PASS
LCDoutPg{3}		PASS
RecordAttempts		DONE

210000384 Overall Result - PASS

Signed: 

Date: 13 Feb 2019

This record was printed from the Sigma Quest Data Archive *cep* 13 Feb 2019

END OF DATA

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Iteration No.: 00

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