

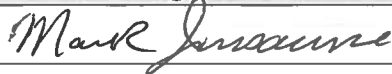
Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Installation Qualification Report	
Report No: TE82964-1-IQR		Iteration No: 01	SAP No: TE0082964QX

INSTALLATION QUALIFICATION REPORT
 For the 2489 ACQUITY TUV Pre-test Download Station (TE82964-1)

PREPARED BY

Name	Role	Signature	Date
James J. Stors	Senior Test Validation Engineer		29 JAN 2018

REVIEWED BY

Name	Role	Signature	Date
Mark Jussaume	Senior Test Engineer		29 JAN 2018

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		29 Jan 2018

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.
01	James J. Stors	Firmware change based on the Denim Driver Pack Project.

1.0 Purpose

The 2489 ACQUITY TUV Pre-Test Download Station (TE82964-1) is located at Contract Manufacturer Flextronics in Singapore. The system is designed to download instrument firmware and assign the instrument serial number for 2489 and ACQUITY TUV Detectors and has been classified as Fit for Use.

2.0 Scope of Report

This Installation Qualification is being performed as required by Project DENIM. This Installation Qualification Report details the requalification activities undertaken for the 2489 ACQUITY TUV Pre-test Download Station (TE82964-1) based on the requirements of the Installation Qualification Procedure, 730004135 Ver. 00, per TE82964-1-22JAN18-VAF.

The Denim Project results in a change of firmware loaded onto TUV Detector Models 186015028 and 186015031, which will be verified through the Execution of Test Script 04 – Test Software and Instrument Firmware Version, as follows:

- Model 186015028, ACQUITY UPLC TUV Detector will require Firmware 1.70.2710.
- Model 186015031, ACQUITY UPLC TUV Detector TC will require Firmware 1.70.2698.

3.0 Summary of Results - Statement of Fitness for Intended Use

The 2489 ACQUITY TUV Pre-test Download Station was tested in accordance with Installation Qualification Procedure, 730004135 Ver. 00, per TE82964-1-22JAN18-VAF. The required Test Script was performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the 2489 ACQUITY TUV Pre-test Download Station complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the 2489 ACQUITY TUV Pre-test Download Station (TE82964-1) remains fully qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
IQ	Installation Qualification
IQR	Installation Qualification Report
N/A	Not Applicable
ECR	Engineering Change Request
BOM	Bill of Material
TSP	Test Specification and Procedure
cGMP	Current Good Manufacturing Practice
VAF	Validation Assessment Form
UPLC	Ultra Performance Liquid Chromatography
UUT	Unit Under Test
TUV	Tunable UV/Vis Absorbance Detector
SAP	Enterprise Resource Planning (ERP) software

5.0 Training

The Executor of the 730004135, Installation Qualification Procedure, is the Author and is therefore trained. The Executor was trained to 735001617, 2489 – ACQUITY TUV Download/Pre-test Test Specification and Procedure (TSP) and a Training Record is provided as Attachment 7.1.

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6.0 Qualification Results

6.1 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 00, per TE82964-1-22JAN18-VAF. The completed Test Script Data Sheet is provided as Attachment 7.2.

6.1.1 Per ECR 9219848, the BOM of Model 186015028, ACQUITY UPLC TUV Detector, has been modified to specify Firmware Version 1.70.2710. A screen capture of the BOM from SAP showing the Firmware is provided below:

Display material BOM: General Item Overview

Subitems | New Entries | Header | Validity

Material: 186015028 ACQUITY UPLC TUV Detector F

Plant: US31 Manufacturing Milford, US

Alternative BOM: 1

Item	ICt	Component	Component description	Quantity	Un	A...	Sts	Valid From	Valid to	Change No.	P...	SortStrng	Item ID	Chg No. To	G.	R	Fl...	L...
0010	I	279001066	ASSEMBLY, DETECTOR TUV-E	1	EA			09/27/2005	12/31/9999	9117599			00000001					
0020	I	200000202	Kit, Startup, ACQUITY UPLC TUV, Det.	1	EA			09/27/2005	12/31/9999	9117599			00000002					
0040	I	WAT006277	LABEL, CONGRATULATIONS	1	EA			09/27/2005	12/31/9999	9117599			00000004					
0050	I	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA			09/27/2005	12/31/9999	9117599			00000005					
0060	I	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA			09/27/2005	12/31/9999	9117599			00000006					
0070	I	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	1	EA			09/27/2005	12/31/9999	9117599			00000007					
0090	I	205000355	ACQUITY UPLC Multi Det. Drip Tray	1	EA			09/27/2005	12/31/9999	9117599			00000009					
0100	I	290000730	BOX, SHIPPING, TUVE	1	EA			11/04/2005	12/31/9999	9118655			00000010					
0110	I	716001892	Info. Set, ACQUITY UPLC TUV Detector	1	EA			11/04/2005	12/31/9999	9118655			00000011					
0120	I	WAT027033	CABLE TIE MINIATURE	1	EA			08/10/2009	12/31/9999	9144155			00000012					
0130	I	WAT089533	BAG, POLY 2ML	1	EA			08/10/2009	12/31/9999	9144155			00000013					
0150	L	361000749	ACQUITY TUV Firmware 1.70.2710	1	EA			01/24/2018	12/31/9999	9219848			NON-ISSUE	00000015				

6.1.2 Per ECR 9219848, the BOM of Model 186015031, ACQUITY UPLC TUV Detector TC, has been modified to specify Firmware Version 1.70.2698. A screen capture of the BOM from SAP showing the Firmware is provided below:

Display material BOM: General Item Overview

Subitems | New Entries | Header | Validity

Material: 186015031 ACQUITY UPLC TUV Detector TC E

Plant: US31 Manufacturing Milford, US

Alternative BOM: 1

Item	ICt	Component	Component description	Quantity	Un	A...	Sts	Valid From	Valid to	Change No.	P...	SortStrng	Item ID	Chg No. To	G.	R	Fl...	L...
0010	I	WAT006277	LABEL, CONGRATULATIONS	1	EA			01/29/2010	12/31/9999	9149483			00000001					
0020	I	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA			01/29/2010	12/31/9999	9149483			00000002					
0030	I	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA			01/29/2010	12/31/9999	9149483			00000003					
0040	I	WAT027033	CABLE TIE MINIATURE	1	EA			01/29/2010	12/31/9999	9149483			00000004					
0050	I	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	1	EA			01/29/2010	12/31/9999	9149483			00000005					
0060	I	WAT089533	BAG, POLY 2ML	1	EA			01/29/2010	12/31/9999	9149483			00000006					
0070	I	200000260	Kit, Startup, ACQUITY UPLC Detector	1	EA			01/29/2010	12/31/9999	9149483			00000007					
0080	I	205000355	ACQUITY UPLC Multi Det. Drip Tray	1	EA			01/29/2010	12/31/9999	9149483			00000008					
0090	I	290001213	BOX, SHIPPING, TUV-GP	1	EA			04/01/2010	12/31/9999	9151001			00000009					
0100	I	716002762	Info. Set, ACQUITY UPLC TUV Detector	1	EA			01/29/2010	12/31/9999	9149483			00000010					
0110	I	279001743	ASSY, DETECTOR, ACQUITY TUV	1	EA			01/29/2010	12/31/9999	9149483			00000011					
0130	L	361000750	ACQUITY TUV II Firmware 1.70.2698	1	EA			01/24/2018	12/31/9999	9219848			NON-ISSUE	00000014				

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- 6.1.3 The test station was used to download Firmware for the Model 186015028, ACQUITY UPLC TUV Detector. The Firmware loaded by the system was verified using HyperTerminal and met the requirement of loading Version 1.70.2710, as shown in the screen capture below:

```

38400 BPS Terminal - HyperTerminal
File Edit View Call Transfer Help
[Icons]
CONSOLE:>
CONSOLE:>
CONSOLE:> version
e2487 or ACQUITY TUV, 1.70.2710 (Oct 17 2017)
CONSOLE:> _
Connected 4:51:57 Auto detect 38400 8-N-1 SCROLL CAPS NUM Cap
  
```

- 6.1.3.1 Model 186015028, ACQUITY UPLC TUV Detector, as specified by TE82964-1-22JAN18-VAF, was not available for testing during the execution of Test Script IQ-04: Software and Instrument Firmware Version, as summarized in Section 8.0, Deviation from Test Equipment Qualification.
- 6.1.4 The test station was used to download Firmware onto one (1) Model 186015031 UUT. The Firmware loaded by the system was verified using HyperTerminal and met the requirement of loading Version 1.70.2698, as shown in the screen capture below:

```

38400 BPS Terminal - HyperTerminal
File Edit View Call Transfer Help
[Icons]
CONSOLE:>
CONSOLE:>
CONSOLE:> version
e2487 or ACQUITY TUV, 1.70.2698 (Oct 17 2017)
CONSOLE:> _
Connected 6:26:50 Auto detect 38400 8-N-1 SCROLL CAPS NUM Cap
  
```

- 6.2 A summary of the attached objective evidence is provided in the Table below:

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-04	Pass	Attachments 7.2	Section 8.1 – Deviation #1

7.0 Attachments

- 7.1 Training Record for 735001617, 2489 – ACQUITY TUV Download/Pre-test Test Specification and Procedure
- 7.2 IQ-04: Test Software and Instrument Firmware Version Test Script Data Sheet

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8.0 Deviation from Test Equipment Qualification

There was one deviation found during the execution of the Installation Qualification Procedure 730004135 Ver. 00, per TE82964-1-22JAN18-VAF, for TE82964-1, 2489 ACQUITY TUV Pre-Test Download Station.

8.1 Deviation #1

Description: TE82964-1-22JAN18-VAF requires the loading of the new Firmware Version 1.70.2710 onto one (1) Model 186015028, ACQUITY UPLC TUV Detector. The required UUT Model was not available for testing during the execution of Test Script IQ-04: Software and Instrument Firmware Version.

Corrective Action: A Model N2971036 A-30 UV Detector was used for the Firmware Version 1.70.2710 verification test. The Executor used the test station to download Firmware Version 1.70.2710 onto the Model N2971036 A-30 UPLC TUV Detector by selecting Model 186015028, ACQUITY UPLC TUV Detector.

Resolution: The Corrective Action defined above is acceptable as the N2971036 A-30 UV Detector is functionally similar to the Model 186015028, ACQUITY UPLC TUV Detector, enabling the system to load the new Firmware that is being verified by this test. The intent of the test is to verify that the new Firmware Version 1.70.2710 loaded onto the Detector when Model 186015028, ACQUITY UPLC TUV Detector is selected. Since the Firmware Version 1.70.2710 was verified to have been loaded onto the UUT, as detailed in Section 6.1.3. the Deviation does not affect the overall Passing result.

9.0 References

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

Document Number	Document title
730004135, Ver. 00	Installation Qualification Procedure
735001617, Ver. 09	2489 – ACQUITY TUV Download/Pre-test Test Specification and Procedure
ECR 9219848	Engineering Change Request for Project DENIM
TE82964-1-22JAN18-VAF	Validation Assessment Form for Project DENIM TUV Implementation

Title: Installation Qualification Procedure

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IOQ Test name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04	
Equipment No./ID: TE82964-1		Equipment Name: 2489 ACQUITY TUV Pre-Test Download Station		
Installation Site: Contract Manufacturer Flextronics, Singapore				
Purpose: To verify that the installed firmware/software is correct per the applicable design/operational documents (TSP, ASP, MPR, BOM, and/or other Design documents). Test execution: List all critical instruments/components and/or sub-systems that require software and/or firmware in the Description column. List the associated required software/firmware version, as defined in the applicable design/operational documents, in the Acceptance criteria column. Verify that the software/firmware version on the Test Equipment match the acceptance criteria and are identical. Enter N/A for any parameter or cell that is not used or applicable. Objective evidence: Completed Test Script Data Sheet Identify the applicable design/operational document that defined the required software/firmware version(s) in the associated Installation Qualification Report.				
Description	Acceptance criteria	As found	Pass/Fail	Initial & Date
Model 186015028, ACQUITY UPLC TUV Detector Firmware	Version: 1.70.2710	Version: 1.70.2710	PASS	AK 29 JAN 2018
Model 186015031, ACQUITY UPLC TUV Detector TC Firmware	Version: 1.70.2698	Version: 1.70.2698	PASS	AK 25 JAN 2018
Comments: MODEL N2971036 A-30 UV DETECTOR USED FOR FIRMWARE VERSION 1.70.2710 TEST AS SUMMARIZED IN SECTION 8.1, DEVIATION #1 OF THE TEST REPORT. N/A James J. Stone 29 JAN 2018				
Overall Test Conclusion: ☒ Pass ☐ Fail				

Copy this Test Script as needed