

 THE SCIENCE OF WHAT'S POSSIBLE.™		Installation Qualification Report	
Report No: TE83057-4-IQR	Iteration No: 02	SAP No: TE0083057QX	

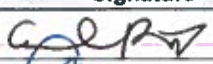
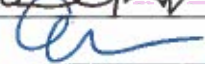
INSTALLATION QUALIFICATION REPORT

For the PDA Detector Download Station (TE83057-4)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		11 Jul 2018

REVIEWED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		11 Jul 2018
Eric Turner	Principal Test Engineer		11 July 2018

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		11 Jul 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	Emma Pierce	Firmware update
02	Luo HuaZhen	Firmware update

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1.0 Purpose

The PDA Detector Download Station (TE83057-4) is located in the Flextronics Contract Manufacturer Site in Singapore. This station is used to download instrument firmware to the following part numbers: 186015026, 186002998, 186015032, 186015033, 186015030, 700002787, 700004035, 700005424, 700005427, 186299800, N2971013, N2971035, 186020003, 186017003, 279002655, and 186017013. After the instrument firmware download is complete, the UUT is moved to the PDA / eLambda Linearity Test System (TE82969) to undergo wavelength calibration, then to the 2998 Final Test System (TE82882) to test noise, drift, and optics

The PDA Detector Download Station is equipped with a computer and the appropriate cables to connect the UUT to the computer. Once the UUT is connected, the operator selects the appropriate part number from the test software and begins the download. When the download is complete a test record is automatically generated and a hard copy is printed for the operator to collect.

This Installation Qualification is being performed as required by the Validation Assessment Form TE83057-06JUL2018-VAF which can be found in the TE0083057QX directory of SAP.

2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the PDA Detector Download Station (TE83057-4) based on the requirements of the Installation Qualification Procedure 730004135, Ver. 00 and TE83057-06JUL2018-VAF.

This Installation Qualification Report defines the documents used to qualify the PDA Detector Download Station (TE83057-4).

3.0 Summary of Results - Statement of Fitness for Intended Use

The PDA Detector Download Station was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 00 and TE83057-06JUL2018-VAF. All required Test Scripts were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the PDA Detector Download Station complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the PDA Detector Download Station (TE83057-4) can be considered qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
ECR	Engineering Change Request
IQ	Installation Qualification
IQR	Installation Qualification Report
N/A	Not Applicable
P/N	Part Number
PDA	Photo Diode Array
S/N	Serial Number
SAP	Enterprise Resource Planning Software
UPLC	Ultra Performance Liquid Chromatography
UUT	Unit Under Test

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Term	Explanation
VAF	Validation Assessment Form
WPPL	Waters Pacific Private Limited

5.0 Training

The operator of the PDA Detector Download Station (TE83057-4) was trained according to the PDA Final Test Procedure 735001613, Ver. 19. The executor of this qualification was trained according to the Installation Qualification Procedure 730004135, Ver. 00. Both training records are provided as Attachments 7.1 and 7.2, respectively.

6.0 Qualification Results

6.1 Test Script IQ-01: Associated Documentation Verification, Test Script IQ-02: Site Verification, and Test Script IQ-03: Instrumentation Calibration Verification were not performed according to TE83057-06JUL2018-VAF.

6.2 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.2.1 The TE83057 Test Equipment Software version listed in PDA Final Test Procedure 735001613, Ver. 19 is Test Software 1.4 and was verified to match the version listed on the test records. The test records are provided as Attachments 7.5, 7.6, 7.7, 7.8, 7.9 and 7.10.

6.2.2 The firmware version listed in ECR #9222852 for part numbers 186015032 and 186015033, is version 1.70.6367 and was verified to match the version listed on the test records. The test records are provided as Attachments 7.5 and 7.6.

6.2.3 The firmware version listed in ECR #9222852 for part numbers 186017003, 186017013, 186002998 and 186299800, is version 1.70.6363 and was verified to match the version listed on the test records. The test records are provided as Attachments 7.7, 7.8, 7.9 and 7.10.

6.3 Test Script IQ-05: General Safety and Alarms was not performed according to TE83057-06JUL2018-VAF.

6.4 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00 and TE83057-06JUL2018-VAF. The completed Test Script Data Sheets are provided as Attachments 7.4.

6.4.1 One (1) UUT (P/N: 186015032, S/N: G18UPD512A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.5.

6.4.2 One (1) UUT (P/N: 186015033, S/N: G18UPL056A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.6.

6.4.3 One (1) UUT (P/N: 186017003, S/N: G18VPD394A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.7.

6.4.4 One (1) UUT (P/N: 186017013, S/N: G18BPD043A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.8.

6.4.5 One (1) UUT (P/N: 186002998, S/N: G18998785A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.9.

6.4.6 One (1) UUT (P/N: 186299800, S/N: G18998771A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.10.

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6.5 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-04	Pass	Attachments 7.3, 7.5,7.6, 7.7,7.8, 7.9 and 7.10	None
IQ-06	Pass	Attachments 7.4, 7.5,7.6, 7.7,7.8, 7.9 and 7.10	None

7.0 Attachments

7.1 Completed Operator Training Record 735001613, Ver. 19

7.2 Completed Executor Training Record 730004135, Ver. 00

7.3 Completed Test Script IQ-04: Test Software and Instrument Firmware Version

7.4 Completed Test Script IQ-06: Functional Verification

7.5 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186015032 (S/N: G18UPD512A)

7.6 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186015033 (S/N: G18UPL056A)

7.7 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186017003 (S/N: G18VPD394A)

7.8 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186017013 (S/N: G18BPD043A)

7.9 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186002998 (S/N: G18998785A)

7.10 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186299800 (S/N: G18998771A)

8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the Installation Qualification Procedure 730004135, Ver. 00.

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
735001613, Ver. 19	PDA Final Test Procedure
721007611, Ver. 01	2998 PDA Detector Functional Specification
TE0083057QX	Validation Assessment Form TE83057-06JUL2018-VAF
ECR #9222852	Engineering Change Request to Release Firmware Update

Training Type:	Read and Understood		
Name:	JOEL MANABATED DEDUYO	Employee ID:	246154
Date of Training	10 JUL 2018		
Comments:	NA		

[illegible]

	SENIOR ENGINEER (TEST)	10 JUL 2018
Employee's Signature	Title	Date
	N/A - SELF TRAINED 	10 JUL 2018
Trainer's Signature	Title	Date

Document No.: TE83057-4-IQR
Iteration No.: 02
Attachment: 7.1 Page: 1 of 1

[†] Without preceding "90"

Title: Individual Training Form

Document No: 730002657

Version No: 00

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Training Type:	Read and Understood		
Name:	Luo Huazhen	Employee ID¹	618078
Date of Training	18 Apr 2018		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	00

	Senior Test Engineer	18 Apr 2018
Employee's Signature	Title	Date
	N/A - self trained	18 Apr 2018
Trainer's Signature	Title	Date

Document No.: TE83057-4-IQR
 Iteration No.: 02
 Attachment: 7.2 Page: 1 of 1

¹ Without preceding "90"

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test Name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04	
Equipment No./ID: TE83057-4		Equipment Name: PDA Detector Download Station		
Installation Site: Flextronics: WPPL, 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
Test Equipment Software	Version: 1.4	Version: 1.4	Pass	HZ 11 Jul 2018
Firmware Version P/N: 186015032	Version: 1.70.6367	Version: 1.70.6367	Pass	HZ 11 Jul 2018
Firmware Version P/N: 186015033	Version: 1.70.6367	Version: 1.70.6367	Pass	HZ 11 Jul 2018
Firmware Version P/N: 186017003	Version: 1.70.6363	Version: 1.70.6363	Pass	HZ 11 Jul 2018
Firmware Version P/N: 186017013	Version: 1.70.6363	Version: 1.70.6363	Pass	HZ 11 Jul 2018
Firmware Version P/N: 186002998	Version: 1.70.6363	Version: 1.70.6363	Pass	HZ 11 Jul 2018
Firmware Version P/N: 186299800	Version: 1.70.6363	Version: 1.70.6363	Pass	HZ 11 Jul 2018
Comments: Software version specified in 735001613, Rev. U, Ver. 19 Firmware versions specified in ECR #9222852 N/A HZ 11 Jul 2018				
Overall Test Conclusion: ☒ Pass ☐ Fail				

Copy this Test Script as needed

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Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.
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Document No.: TE83057-4-IAR
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Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test Name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE83057-4		Equipment Name: PDA Detector Download Station	
Installation Site: Flextronics: WPPL, Singapore			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality.			
Test Execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable.			
Objective Evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance Criteria	Pass/Fail	Initial & Date
UUT Part Number: 186015032 UUT Serial Number: 618UPD512A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 11 Jul 2018
UUT Part Number: 186015033 UUT Serial Number: 618UPLO56A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 11 Jul 2018
UUT Part Number: 186017003 UUT Serial Number: 618UPD394A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 11 Jul 2018
UUT Part Number: 186017013 UUT Serial Number: 618BPD043A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 11 Jul 2018
UUT Part Number: 186002998 UUT Serial Number: 618998785A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 11 Jul 2018
UUT Part Number: 186299800 UUT Serial Number: 618998771A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 11 Jul 2018
Comments: N/A HZ 11 Jul 2018			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

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Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

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Waters Corporation - Test Record

Part Number: 186015032

Operator: 246154

Serial Number: G18UPD512A

Test System: Download-Configure System

Test Software: 1.4

Product: PDA Detector

Start Time: 07/10/2018, 10:30:

End Time: 07/10/2018, 10:37:

Order: NA

Location: Flextronics, SG

TMD: NA

Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Firmware Download		Complete			PASS
Serial Number Set		Complete			PASS
Leak Detector Test		Passed			PASS
Electrical Safety		Passed			PASS

Acquity PDA Download-Config Overall Result - PASS

Signed:



Date:

10 JUL 2018

END OF DATA

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Waters Corporation - Test Record

Part Number: 186015033

Operator: 246154

Serial Number: G18UPL056A

Test System: Download-Configure System

Test Software: 1.4

Product: eLambda Detector

Start Time: 07/10/2018, 13:47:

End Time: 07/10/2018, 13:53:

Order: NA

Location: Flextronics, SG

TMD: NA

Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Firmware Download		Complete			PASS
Serial Number Set		Complete			PASS
Leak Detector Test		Passed			PASS
Electrical Safety		Passed			PASS

**Acquity eLambda Download-Config Overall Result -
PASS**

Signed:



Date:

10 JUL 2018

END OF DATA

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Waters Corporation - Test Record

Part Number: <u>186017003</u>	Product: <u>Acquity Arc PDA Detector</u>
Operator: <u>246154</u>	Start Time: <u>07/10/2018, 10:43:</u>
Serial Number: <u>G18VPD394A</u>	End Time: <u>07/10/2018, 10:48:</u>
Test System: <u>Download-Configure System</u>	Order: <u>NA</u>
Test Software: <u>1.4</u>	Location: <u>Flextronics, SG</u>

TMD: NA

Firmware: 1.70 Build#: 6363 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Firmware Download		Complete			PASS
Serial Number Set		Complete			PASS
Electrical Safety		Passed			PASS

**Acquity Arc PDA Download-Config Overall Result -
PASS**

Signed:



Date:

16 JUL 2018

END OF DATA

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Waters Corporation - Test Record

Part Number: <u>186017013</u>	Product: <u>Acquity Arc Bio PDA Detector</u>
Operator: <u>246154</u>	Start Time: <u>07/10/2018, 13:38:</u>
Serial Number: <u>G18BPD043A</u>	End Time: <u>07/10/2018, 13:43:</u>
Test System: <u>Download-Configure System</u>	Order: <u>NA</u>
Test Software: <u>1.4</u>	Location: <u>Flextronics, SG</u>

TMD: NA

Firmware: 1.70 Build#: 6363 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Firmware Download		Complete			PASS
Serial Number Set		Complete			PASS
Electrical Safety		Passed			PASS

**Acquity Arc Bio PDA Download-Config Overall Result -
PASS**

Signed:



Date:

10 JUL 2018

END OF DATA

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Waters Corporation - Test Record

Part Number: 186002998

Product: 2998 Detector

Operator: 246154

Start Time: 07/10/2018, 13:58:

Serial Number: G18998785A

End Time: 07/10/2018, 14:04:

Test System: Download-Configure System

Order: NA

Test Software: 1.4

Location: Flextronics, SG

TMD: NA

Firmware: 1.70 Build#: 6363 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Firmware Download		Complete			PASS
Serial Number Set		Complete			PASS
Electrical Safety		Passed			PASS

2998 Download-Config Overall Result - PASS

Signed:



Date:

10 JUL 2018

END OF DATA

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Waters Corporation - Test Record

Part Number: <u>186299800</u>	Product: <u>Refresh 2998 Detector</u>
Operator: <u>246154</u>	Start Time: <u>07/10/2018, 14:10:</u>
Serial Number: <u>G18998771A</u>	End Time: <u>07/10/2018, 14:19:</u>
Test System: <u>Download-Configure System</u>	Order: <u>NA</u>
Test Software: <u>1.4</u>	Location: <u>Flextronics, SG</u>

TMD: NA

Firmware: 1.70 Build#: 6363 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Firmware Download		Complete			PASS
Serial Number Set		Complete			PASS
Electrical Safety		Passed			PASS

2998 Download-Config Overall Result - PASS

Signed: 	Date: <u>10 JUL 2018</u>
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END OF DATA

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