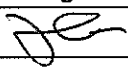


Waters THE SCIENCE OF WHAT'S POSSIBLE™	Installation Qualification Report		
Report No: TE82969-1-IQR	Iteration No: 01	SAP No: TE0082969QX	

INSTALLATION QUALIFICATION REPORT
 For the manual firmware download performed at the PDA / eLambda Linearity Tester (TE82969-1)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		12 Jul 2018

REVIEWED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		
Eric Turner	Principal Test Engineer		

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		

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

The "Reviewed By" signatures denote 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	Luo HuaZhen	Firmware Update

 THE SCIENCE OF WHAT'S POSSIBLE.™		Installation Qualification Report	
Report No: TE82969-1-IQR		Iteration No: 01	SAP No: TE0082969QX

1.0 Purpose

The PDA/ eLambda Linearity Tester (TE82969-1) is located in the Flextronics Manufacturer site in Singapore and is the computer used to download firmware to the following part numbers: 186015034, 186015053, 279002224, and 279002897. The manual firmware download for these part numbers is unrelated to the Linearity and Wavelength Accuracy tests that are the primary purpose of the PDA/ eLambda Linearity Tester (TE82969-1). After the instrument firmware download is complete, the UUT undergoes wavelength calibration and linearity testing using custom software at the TE82969 system, then it is moved to the 2998 Final Test System (TE82882) to test noise, drift, and optics

This Installation Qualification is being performed as required by the Validation Assessment Form TE82969-06JUL2018-VAF which can be found in the TE0082969QX directory of SAP. This qualification is only of the manual firmware download steps as specified in the UPC2 PDA Detector and Veyron PDA Detector Final Test Procedure 735002531, Rev. J, Ver. 09. The linearity test and custom software are not affected and have been qualified; the previous qualification, TE82969-1-IQR_Iteration 00, can be found in the TE0082969QX directory of SAP.

2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the manual firmware download performed at the PDA / eLambda Linearity Tester (TE82969-1) based on the requirements of the Installation Qualification Procedure 730004135, Ver. 00 and TE82969-06JUL2018-VAF.

This Installation Qualification Report defines the documents used to qualify the manual firmware download performed at the PDA / eLambda Linearity Tester (TE82969-1).

3.0 Summary of Results - Statement of Fitness for Intended Use

The manual firmware download performed at the PDA / eLambda Linearity Tester was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 00 and TE82969-06JUL2018-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 manual firmware download performed at the PDA / eLambda Linearity Tester complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the manual firmware download performed at the PDA / eLambda Linearity Tester (TE82969-1) can be considered fully 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
PC	Personal Computer
PDA	Photo Diode Array
SAP	Enterprise Resource Planning Software
S/N	Serial Number
TSP	Test Specification and Procedure
UUT	Unit Under Test

 Installation Qualification Report	
Report No: TE82969-1-IQR	Iteration No: 01
SAP No: TE0082969QX	

Term	Explanation
VAF	Validation Assessment Form

5.0 Training

The operator of the manual firmware download performed at the PDA / eLambda Linearity Tester (TE82969-1) was trained according to the UPC2 PDA and Veyron PDA Final Test Procedure 735002531, Ver. 09. The executor of this qualification was trained according to the Installation Qualification Procedure 730004135, Ver. 00. Both training records are provided as Attachment 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 TE82969-06JUL2018-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 firmware version listed in ECR #9222852 for part numbers 186015034 and 186015053 is 1.70.6367 and was verified to match the version listed on the screen shots of device console. The screen shots of device console are provided as Attachments 7.4 and 7.5.
- 6.3 Test Script IQ-05: General Safety and Alarms was not performed according to TE82969-06JUL2018-VAF.
- 6.4 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.6.

6.4.1 One (1) UUT (P/N: 186015034, S/N: G18C2P393A) was tested using the manual firmware download performed at the PDA / eLambda Linearity Tester (TE82969-1) with all tests passing. Refer to Attachment 7.7 for the passing Test Record.

6.4.2 One (1) UUT (P/N: 186015053, S/N: G18ADT145A) was tested using the manual firmware download performed at the PDA / eLambda Linearity Tester (TE82969-1) with all tests passing. Refer to Attachment 7.8 for the passing Test Record.
- 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 7.4, and 7.5	None
IQ-06	Pass	Attachments 7.7 and 7.8	None

7.0 Attachments

- 7.1 Completed Operator Training Record 735002531, Ver. 09
- 7.2 Completed Executor Training Record 730004135, Ver. 00
- 7.3 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.4 Objective Evidence IQ-04: The Screen Shot for UUT Part #186015034 (G18C2P393A)
- 7.5 Objective Evidence IQ-04: The Screen Shot for UUT Part #186015053 (G18ADT145A)
- 7.6 Completed Test Script IQ-06: Functional Verification
- 7.7 Objective Evidence IQ-06: Passing Final Test Record for UUT Part #186015034 (G18C2P393A)
- 7.8 Objective Evidence IQ-06: Passing Final Test Record for UUT Part #186015053 (G18ADT145A)

 THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE82969-1-IQR	Iteration No: 01	SAP No: TE0082969QX	

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
735002531, Ver. 09	UPC2 PDA and Veyron PDA Final Test Procedure
TE0082969QX	Validation Assessment Form TE82969-06JUL2018-VAF
TE0082969QX	Installation Qualification TE82969-1-IQR-Iteration 00
ECR #9222852	Engineering Change Request for Firmware Release

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	KWEK CHOCK MENG	Employee ID ¹	842185
Date of Training	10 JUL 2018		
Comments:	N/A		

Document Number	Title	Rev. #
735002531	UPC2 PDA Detector and Veyron PDA Detector Final Test Procedure	J


TECHNICIAN
10 JUL 2018
 Employee's Signature Title Date

NA - SELF TRAINED

10 JUL 2018
 Trainer's Signature Title Date

Document No.: TE82969-1-IQR
 Iteration No.: 01
 Attachment: 7.1 Page: 1 of 1

¹ Without preceding "90"

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Luo Huazhen	Employee ID ¹	618078
Date of Training	18 Apr 2018		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	00
N/A 18 Apr 2018		


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.: TE82969-1-IQR
 Iteration No.: 01
 Attachment: 7.2 Page: 1 of 1

¹ Without preceding "90"

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 1 of 2

IQ Test Name: Test Software and Instrument Firmware Version		Test Script No.: IQ-04		
Equipment No./ID: TE82969-1		Equipment Name: PDA/ eLambda Linearity Test System		
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
Firmware Version P/N: 186015034	Version: 1.70.6367	Version: 1.70.6367	Pass	HZ 12Jul 2018
Firmware Version P/N: 186015053	Version: 1.70.6367	Version: 1.70.6367	Pass	HZ 12Jul 2018
Comments: Firmware versions specified in ECR #9222852 N/A HZ 12Jul 2018				
Overall Test Conclusion: ☒ Pass ☐ Fail				

Copy this Test Script as needed

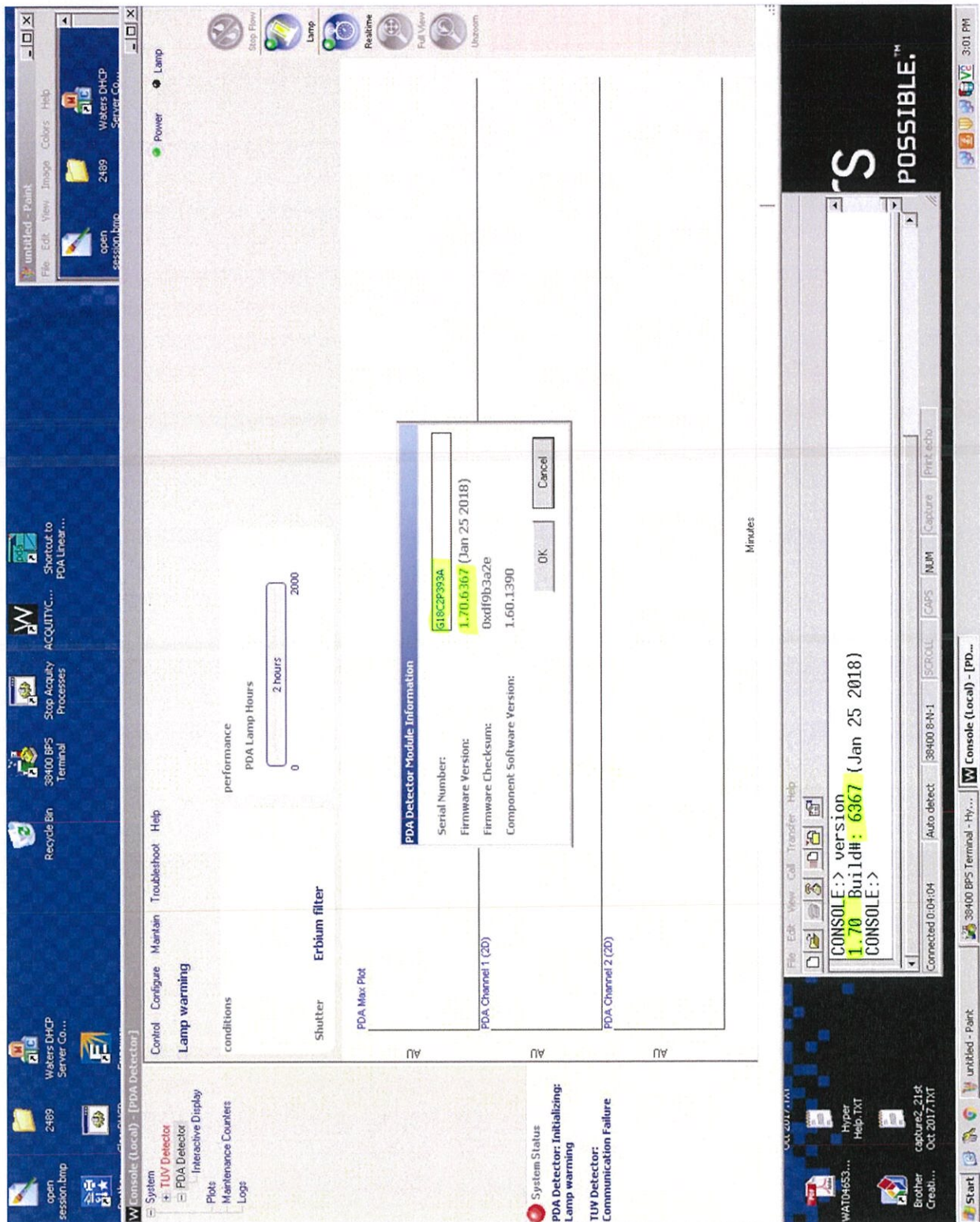
Waters Confidential

Template 730000483 V06

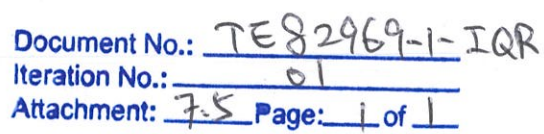
It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Document No.: TE82969-1-IQR
Iteration No.: 01
Attachment: 7.3 Page: 1 of 1



Document No.: TE82969-1-1QR
 Iteration No.: 01
 Attachment: 7-4 Page: 1 of 1



Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 2 of 2

IQ Test Name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE82969-1		Equipment Name: PDA/ eLambda Linearity Test System	
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: 186015034 UUT Serial Number: G18C2P393A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 12Jul 2018
UUT Part Number: 186015053 UUT Serial Number: G18ADT145A	All required CTQ Specification measurements result in a Pass.	Pass	HZ 12Jul 2018
Comments: N/A HZ 12Jul 2018			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.
HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Document No.: TE82969-1-IQR
Iteration No.: 01
Attachment: 7.6 Page: 1 of 1

WATERS CORPORATION
INSTRUMENT - FINAL TEST RECORD

Part Number: <u>186015034</u>	Description: <u>ACQUITY UPLC PDA DETECTOR</u>
Tested By: <u>KWEK CHOCK MENG</u>	Date: <u>10 JUL 2018</u>
Serial Number: <u>G18C2P393A</u>	Control Number: <u>NA</u>
Software Revision: <u>1.70.6367</u>	Factory Order: <u>NA</u>

Electrical Safety

PASS ☒ FAIL ☐ see note # PASS ☐

FANS

PASS ☒ FAIL ☐ see note # PASS ☐

LED'S FUNCTIONALITY

PASS ☒ FAIL ☐ see note # PASS ☐Linearity (% RSD) Actual: 3.16PASS ☒ FAIL ☐ see note # PASS ☐

Wavelength Accuracy

255nm 254.7 379 378.5 523 522.7PASS ☒ FAIL ☐ see note # PASS ☐

Final Test

PASS ☒ FAIL ☐ see note # PASS ☐Instrument Result: PASS ☒ FAIL ☐ Signed [Signature]Date: 12 JUL 2018Notes: NA

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail, a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing. The initial form must be attached and retained.

END OF DATA

Document No.: TE82969-1-IQR
Iteration No.: 01
Attachment: 7-7 Page: 1 of 4

Waters Corporation - Test Record

Part Number: 186015034

Product: Acquity UPC2 PDA

Operator: 842185

Start Time: 07/12/2018, 15:57:

Serial Number: G18C2P393A

End Time: 07/12/2018, 16:04:

Test System: TE82969-1

Order: NA

Test Software: 2.0

Location: Flextronics,SG

TMD: NA

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

Name	LSL	Measurement	USL	Unit	Outcome
%RSD	0	3.157	5		PASS
Mean		0.09			PASS
Std Dev		0.003			PASS
Lambda		257.85			PASS
A/C 5mg		0.0864			PASS
A/C 10mg		0.091			PASS
A/C 15mg		0.0934			PASS
A/C 20mg		0.0913			PASS
A/C 25mg		0.0896			PASS
A/C 30mg		0.0863			PASS

Acquity UPC2 PDA Linearity Test Overall Result - PASS

Signed:

L. fuzils

Date:

12 JUL 2018

END OF DATA

Document No.: TE82969-1-IQR
Iteration No.: 01
Attachment: 7.7 Page: 2 of 4

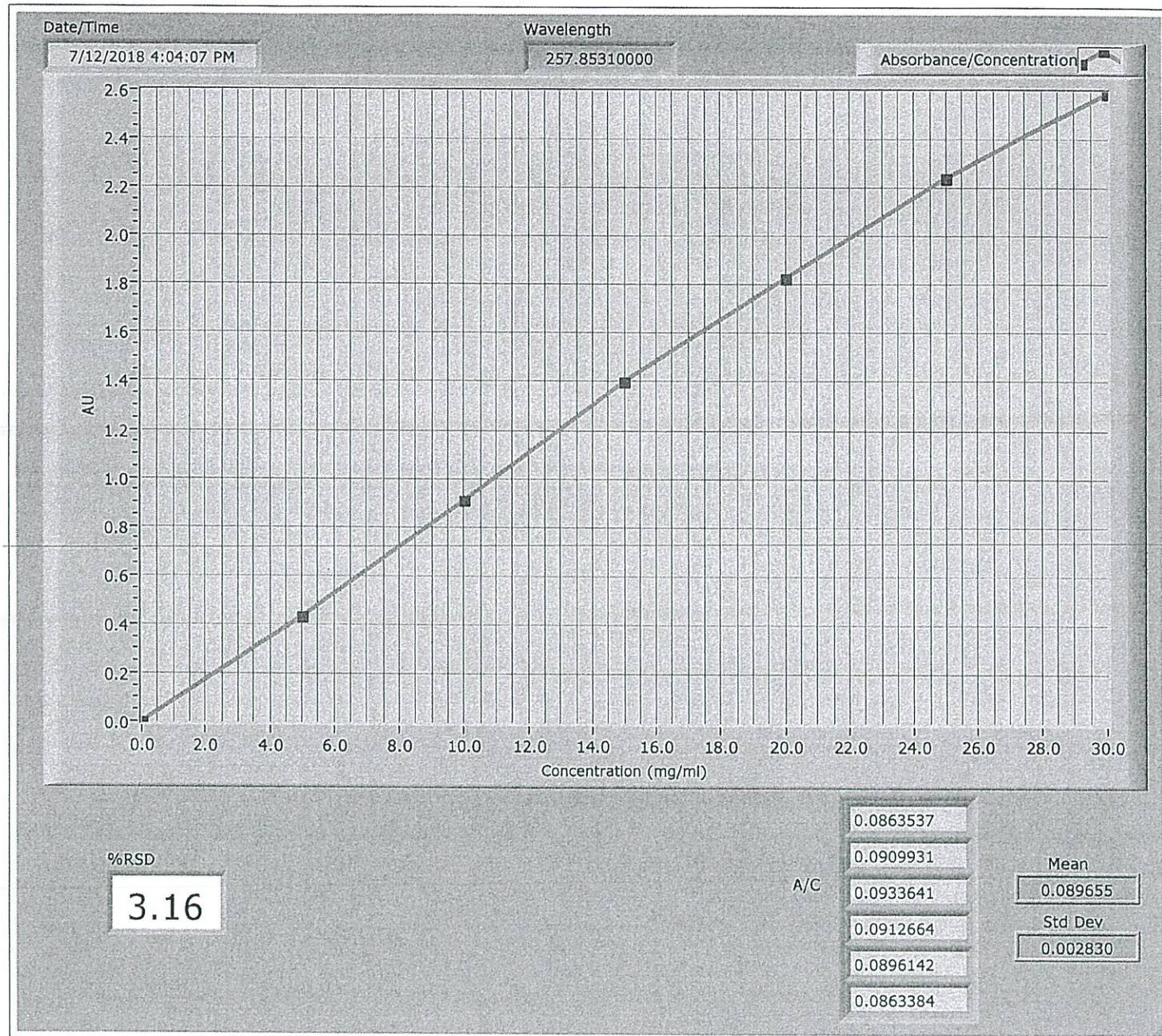


Linearity Graph

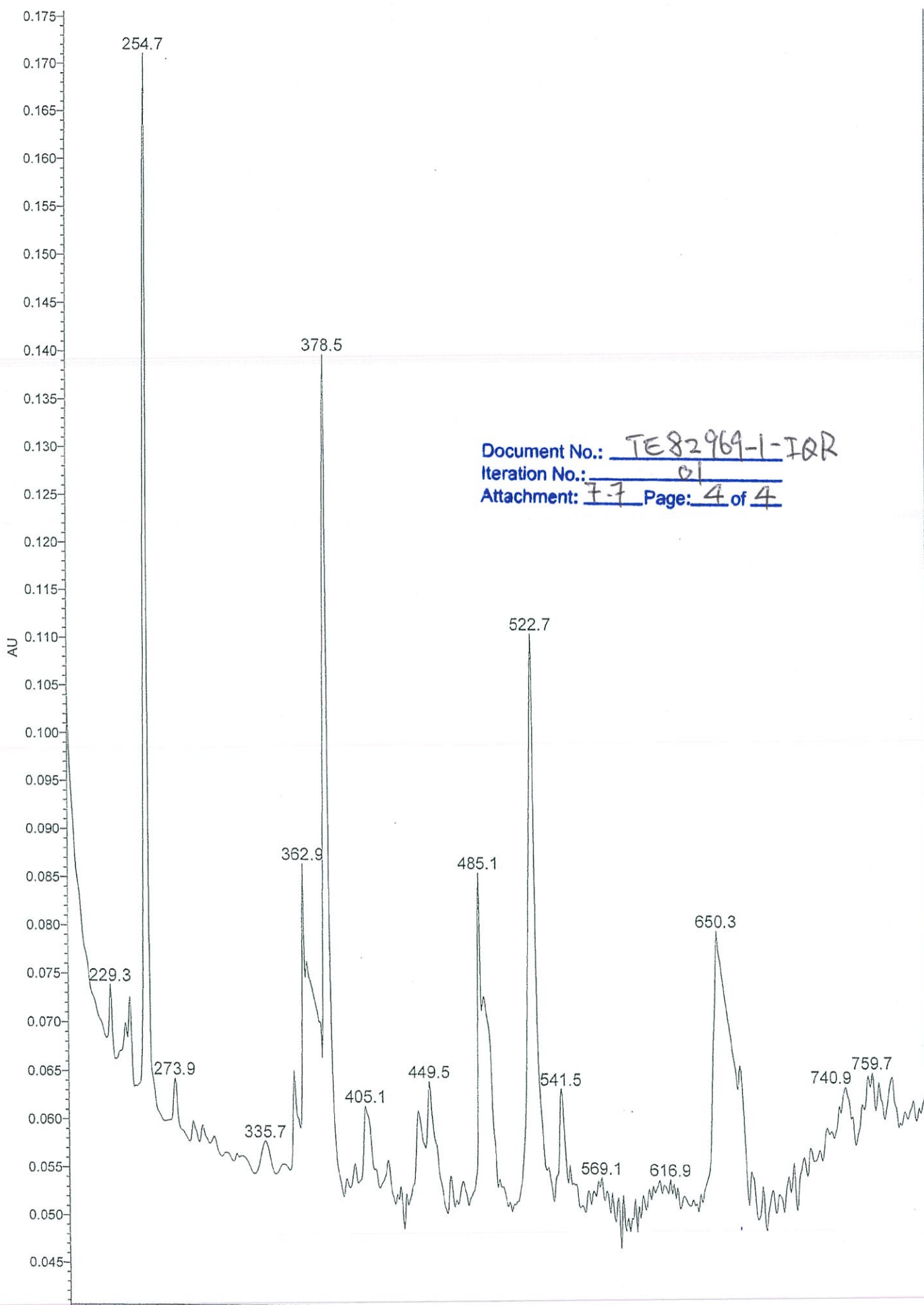
C:\Program Files\PDA Lin\PDA Linearity.exe\CrunchData.vi

Last modified on 7/12/2018 at 4:04 PM

Printed on 7/12/2018 at 4:04 PM



Document No.: TE82969-1-IQR
Iteration No.: 01
Attachment: 7.7 Page: 3 of 4



WATERS CORPORATION INSTRUMENT - FINAL TEST RECORD

Part Number: <u>186015053</u>	Description: <u>ALQUITY PDA DET.W/TAPER SLIT</u>
Tested By: <u>KWEK CHOCK MENG</u>	Date: <u>10 JUL 2018</u>
Serial Number: <u>G18ADT145A</u>	Control Number: <u>NA</u>
Software Revision: <u>1.70.6367</u>	Factory Order: <u>NA</u>

Electrical Safety

PASS ☒ FAIL ☐ see note # PASS ☐

FANS

PASS ☒ FAIL ☐ see note # PASS ☐

LED'S FUNCTIONALITY

PASS ☒ FAIL ☐ see note # PASS ☐

Linearity (% RSD) Actual: 3.18

PASS ☒ FAIL ☐ see note # PASS ☐

Wavelength Accuracy

255nm 254.4 379 378.8 523 523.0

PASS ☒ FAIL ☐ see note # PASS ☐

Final Test

PASS ☒ FAIL ☐ see note # PASS ☐

Instrument Result: PASS ☒ FAIL ☐ Signed [Signature] Date: 12 JUL 2018

Notes: NA

This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail, a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing. The initial form must be attached and retained.

END OF DATA

Document No.: TE82969-1-1QR
Iteration No.: 01
Attachment: 7.8 Page: 1 of 4

Waters Corporation - Test Record

Part Number: 186015053

Product: Acquity Tapered Slit PDA

Operator: 842185

Start Time: 07/12/2018, 15:46:

Serial Number: G18ADT145A

End Time: 07/12/2018, 15:51:

Test System: TE82969-1

Order: NA

Test Software: 2.0

Location: Flextronics,SG

TMD: NA

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

Name	LSL	Measurement	USL	Unit	Outcome
%RSD	0	3.185	5		PASS
Mean		0.089			PASS
Std Dev		0.003			PASS
Lambda		257.53			PASS
A/C 5mg		0.0854			PASS
A/C 10mg		0.0905			PASS
A/C 15mg		0.0929			PASS
A/C 20mg		0.0911			PASS
A/C 25mg		0.0894			PASS
A/C 30mg		0.0866			PASS

Acquity Tapered Slit PDA Linearity Test Overall Result - PASS

Signed:

[Signature]

Date:

12 Jul 2018

END OF DATA

Document No.: TE82969-1-IQR
Iteration No.: 01
Attachment: 7.8 Page: 2 of 4

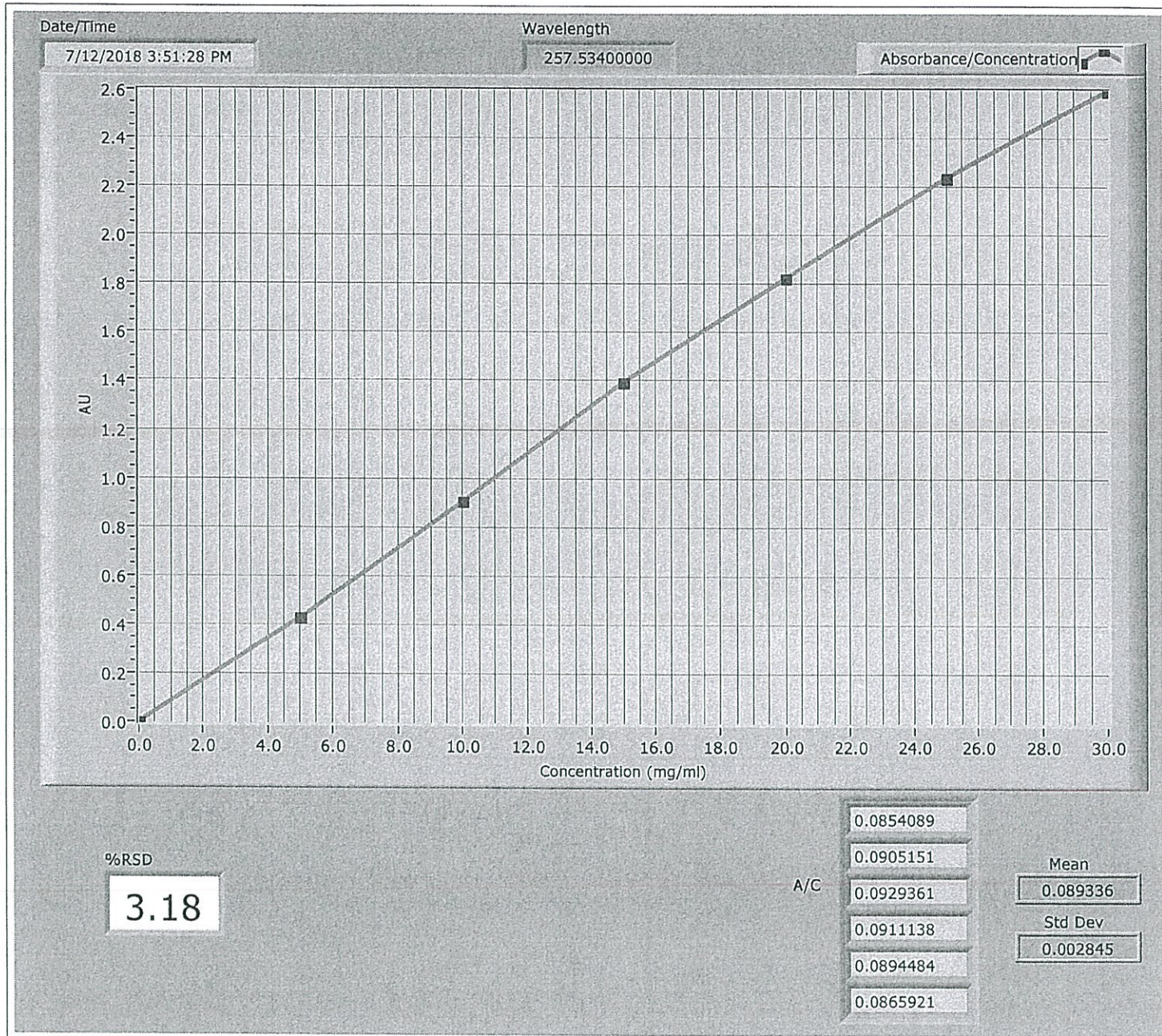


Linearity Graph

C:\Program Files\PDA Lin\PDA Linearity.exe\CrunchData.vi

Last modified on 7/12/2018 at 3:51 PM

Printed on 7/12/2018 at 3:51 PM



Document No.: TE82969-1-IQR
Iteration No.: 01
Attachment: 7.8 Page: 3 of 4

