

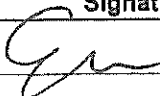
Waters THE SCIENCE OF WHAT'S POSSIBLE.	Installation Qualification Report	
	Report No: TE82969-1-IQR	SAP No: TE008296901

INSTALLATION QUALIFICATION REPORT
For the PDA/eLambda Linearity Tester (TE82969-1)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		28 Jun 2019

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principle Test Engineer		26 July 2019

APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		29 Jul 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.
01	Luo HuaZhen	Firmware Update.
02	Luo HuaZhen	New software version to add the 30mg concentration test.
03	Luo HuaZhen	New software version to add Optics Bench part numbers

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1.0 Purpose

The PDA/eLambda Linearity Tester, TE82969-1, is located in Flextronics Contract Manufacturing Site of WPPL in Singapore. The PDA/eLambda Linearity Tester is used to verify that linearity of PDA Detectors of the following part numbers is within specification: 186015026, 186002998, 186015032, 186015033, 186015030, 186299800, 186017003, 186017013, 186015034, and 186015053 as well as the spares and refurbished equivalent parts as listed in the PDA Final Test TSP 735001613. Note that not all part numbers have a refurbished equivalent or spare. After the UUT has completed the firmware download at the PDA Detector Download Station (TE83057) and has passed the linearity test, it is moved to the 2998 Final Test System (TE82882) to test noise, drift, and optics.

2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the PDA/eLambda Linearity Tester (TE82969-1) based on the requirements of the performed Installation Qualification, 730004135, Version 02 as outlined by the Test Software Version 2.2 risk assessment, per TE82969-10JUN2019-VAF.

The risk assessment, based on this change, resulted in the requirement of performing the following test scripts:

- IQ-01 Associated Documentation Verification: To verify that the PDA Final Test, Test and Specification Procedure, 735001613, that references the new software version, 2.2, is in the appropriate state in SAP.
- IQ-04 Test Software Version: To verify the version specified within the PDA Final Test, Test and Specification Procedure, 735001613, matches the version of the program.
- IQ-06 Functional Verification: To verify that the functionality of the system when running the new part numbers.

All other testing performed, as detailed in TE82969-1-IQR, Iteration 00, remains valid and applicable.

3.0 Summary of Results - Statement of Fitness for Intended Use

The PDA/eLambda Linearity Tester (TE82969-1) was tested in accordance with the applicable sections of the Installation Qualification Protocol, 730004135, Version 02, as outlined in the Test Software Version 2.2 risk assessment, per TE82969-10JUN2019-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/eLambda Linearity Tester (TE82969-1) remains compliant with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the PDA/eLambda Linearity Tester (TE82969-1) remains fully qualified and fit for intended use post the change, as outlined in TE82969-10JUN2019-VAF.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
mg	Milligram
PDA	Photo Diode Array
SAP	Enterprise Resource Planning (ERP) software
TSP	Test Specification and Procedure
UUT	Unit Under Test
VAF	Validation Assessment Form

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5.0 Training

The Executor who performed the PDA/eLambda Linearity Tester (TE82969-1) Installation Qualification was trained according to the Installation Qualification Procedure, 730004135, Version 02. The training record is proved as Attachment 7.1.

The Operator who performed the testing of the UUT using the PDA/eLambda Linearity Tester (TE82969-1) per Installation Qualification Procedure, 730004135, Version 02, IQ-06, Functional Verification Test Script, was trained according to the PDA Final Test System Test and Specification Procedure, 735001613, Version 22. The training record is proved as Attachment 7.2.

6.0 Qualification Results

6.1 Test Script IQ-01, Associated Documentation Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 02, for the PDA Final Test System Test and Specification Procedure, 735001613, as outlined in TE82969-10JUN2019-VAF.

6.1.1 IQ-01, Associated Documentation Verification Data Sheet, is provided as Attachment 7.3

6.1.2 The updated PDA Final Test System Test and Specification Procedure, 735001613, Version 22, was confirmed to have been updated with software version 2.2 and to be in SAP with a status of Ready. A screen capture is provided below:

Document List After Selection 24 Hits

Rev.	Type	Document	Vs Part	Description	Status text	Current	Valid From	Valid To	Change No.	Long name
Select All	TSP	735001613	00 000	Acquity PDA Final Test	RELEASE GENERAL		25.06.2007	30.03.2008		Eric Turner
B	TSP	735001613	01 000	Acquity PDA Final Test	ABANDON					Bruce Porter
C	TSP	735001613	02 000	Acquity PDA Final Test	RELEASE GENERAL		31.03.2008	11.05.2008	9134035	Eric Turner
D	TSP	735001613	03 000	Acquity PDA Final Test	RELEASE GENERAL		12.05.2008	09.07.2008	9134937	Eric Turner
E	TSP	735001613	04 000	PDA Final test	RELEASE GENERAL		10.07.2008	03.12.2008	9136327	Eric Turner
F	TSP	735001613	05 000	PDA Final test	RELEASE GENERAL		04.12.2008	29.03.2009	9139040	Eric Turner
G	TSP	735001613	06 000	PDA Final test	RELEASE GENERAL		30.03.2009	21.05.2009	9140911	Eric Turner
H	TSP	735001613	07 000	PDA Final test	RELEASE GENERAL		22.05.2009	01.07.2010	9142852	Eric Turner
I	TSP	735001613	08 000	PDA Final test	RELEASE GENERAL		02.07.2010	22.11.2010	9153554	Eric Turner
J	TSP	735001613	09 000	PDA Final test	RELEASE GENERAL		23.11.2010	04.07.2012	9157158	Chris Green
K	TSP	735001613	10 000	PDA Final test	ABANDON					Eric Turner
L	TSP	735001613	11 000	PDA Final test	RELEASE GENERAL		05.07.2012	09.02.2014	9171410	Eric Turner
M	TSP	735001613	12 000	PDA Final test	RELEASE GENERAL		10.02.2014	18.02.2014	9185711	Chris Green
N	TSP	735001613	13 000	PDA Final test	RELEASE GENERAL		19.02.2014	12.10.2014	9186532	Eric Turner
O	TSP	735001613	14 000	PDA Final test	RELEASE GENERAL		13.10.2014	24.03.2015	9192539	Eric Turner
P	TSP	735001613	15 000	PDA Final test	ABANDON					Eric Turner
Q	TSP	735001613	16 000	PDA Final test	RELEASE GENERAL		25.03.2015	12.07.2015	9195587	Eric Turner
R	TSP	735001613	17 000	PDA Final test	RELEASE GENERAL		13.07.2015	10.12.2015	9198016	Eric Turner
S	TSP	735001613	18 000	PDA Final test	RELEASE GENERAL		11.12.2015	28.11.2017	9202728	Tyler Model
T	TSP	735001613	19 000	PDA Final test	RELEASE GENERAL		29.11.2017	09.09.2018	9218596	Eric Turner
U	TSP	735001613	20 000	PDA Final test	RELEASE GENERAL		10.09.2018	06.12.2018	9224731	Eric Turner
V	TSP	735001613	21 000	PDA Final test	RELEASE GENERAL		07.12.2018	31.12.9999	9226454	Eric Turner
W	TSP	735001613	22 000	PDA Final test	READY					Eric Turner
X	TSP	735001613	23 000	PDA Final test	ABANDON					Eric Turner

6.1.3 The PDA Linearity Test System Preventive Maintenance Procedure, 735003437, Version 00, was confirmed to be in SAP with a status of Release General. A screen capture is provided below:

Document List After Selection 1 Hits

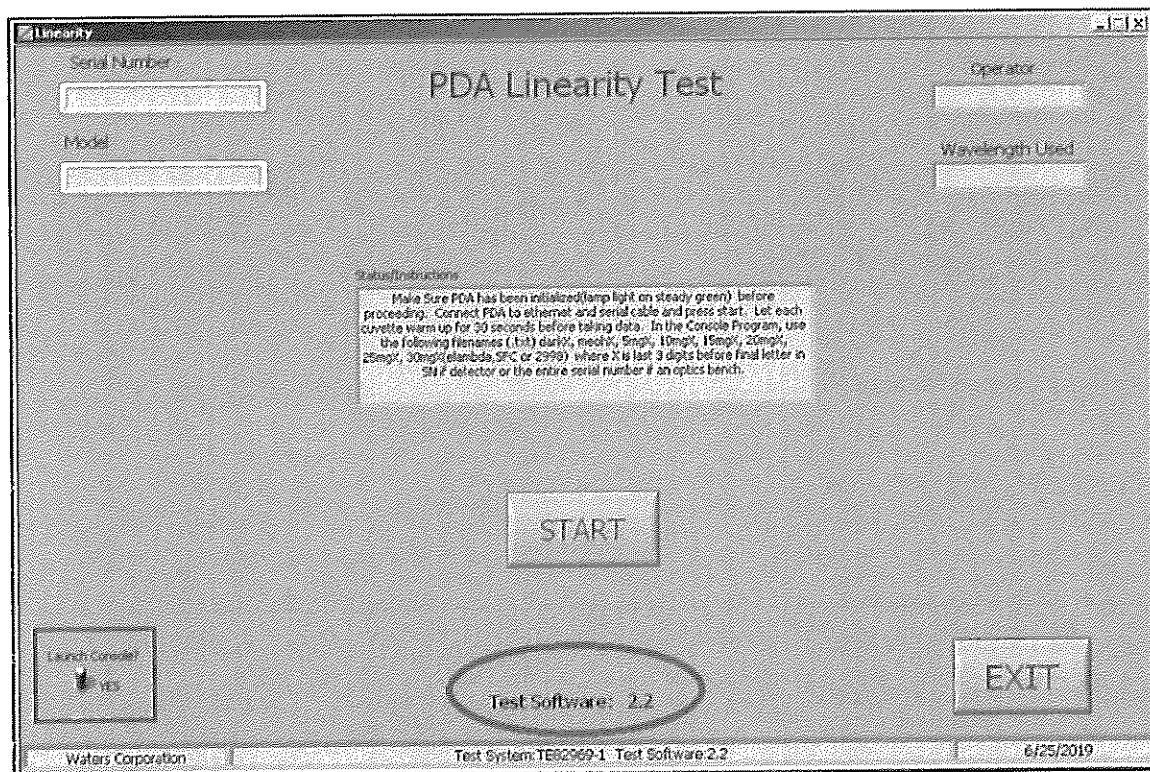
Rev.	Type	Document	Vs Part	Description	Status text	Current	Valid From	Valid To	Change No.	Long name
A	CAL	735003437	00 000	PDA Linearity Test System PM	RELEASE GENERAL		10/24/2014	12/31/9999	9192486	Eric Turner

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6.2 Test Script IQ-04, Test Software and Instrument Firmware Version, was performed in accordance with Installation Qualification Protocol, 730004135, Version 02, for the updated software version 2.2, as outlined in TE82969-10JUN2019-VAF.

6.2.1 IQ-04, Test Software and Instrument Firmware Version Data Sheet, is provided as Attachment 7.4.

6.2.2 The Test Equipment Software version listed in 735001613, PDA Final Test System Test and Specification Procedure (Version 22), is 2.2 and was verified to match the version displayed on the PDA/eLambda Linearity Tester TE82969 program display, as shown in the screen capture below:



6.3 Test Script IQ-06, Functional Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 02, for the updated software version 2.2, as outlined in TE82969-10JUN2019-VAF.

6.3.1 IQ-06, Functional Verification Data Sheet is provided as Attachment 7.5.

6.3.2 One (1) UUT, Part Number 700012245, as required by TE82969-10JUN2019-VAF, was tested using the TE82969-1, PDA/eLambda Linearity Tester, and met the requirement of functionality test and reporting it properly on the Test Record.

6.3.2.1 The Instrument Test Record is provided as Attachment 7.6.

6.3.3 One (1) UUT, Part Number 700012243, as required by TE82969-10JUN2019-VAF, was tested using the TE82969-1, PDA/eLambda Linearity Tester, and met the requirement of functionality test and reporting it properly on the Test Record.

6.3.3.1 The Test Record is provided as Attachment 7.7.

6.4 A summary of the attached objective evidence that applies to each Test Script is provided in the Table below:

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.3	None
IQ-04	Pass	Attachment 7.4	None
IQ-06	Pass	Attachment 7.5, 7.6 and 7.7	None

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7.0 Attachments

- 7.1 Completed Executor Training Record 730004135, Ver.02
- 7.2 Completed Operator Training Record 735001613, Ver.22
- 7.3 IQ-01, Associated Documentation Verification Test Script Data Sheet
- 7.4 IQ-04, Test Software and Instrument Firmware Version Test Script Data Sheet
- 7.5 IQ-06, Functional Verification Test Script Data Sheet
- 7.6 Final Test Record for IQ-06, Part Number: 700012243, Serial Number: 22K6P003
- 7.7 Final Test Record for IQ-06, Part Number: 700012245, Serial Number: 22K4B002

8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the Installation Qualification, 730004135, Version 02, for the PDA/eLambda Linearity Tester (TE82969-1), as outlined in the Test Software Version 2.2 risk assessment, per TE82969-10JUN2019-VAF.

9.0 References

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

Document Number	Document title
730004135	Installation Qualification Protocol
735001613	PDA Final Test System Test and Specification Procedure
735003437	PDA Linearity Test System Preventive Maintenance Procedure
TE82969-10JUN2019-VAF	Test Software Version 2.2 risk assessment

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	01Mar2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	02

	Senior Test Engineer	01Mar2019
Employee's Signature	Title	Date
N/A	Self Trained	01Mar2019
Trainer's Signature	Title	Date

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

¹ Without preceding "90"



WORK INSTRUCTION

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

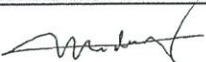
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Appendix A: TRAINING RECORD

Document #	735001613	Document Title	PDA Final Test - Test and Specification Procedure	Version	22
				Revision	N/A

☒ Read and Understood

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
JOEL MAMALATEG DEOLYO		JMD	13 JUN 2019
	N/A		
	 18 JUN 2019		

Document No.: TE82969-1-1QR
Iteration No.: 03
Attachment: 7.2 Page: 1 of 1

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

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Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82969-1	Equipment Name:	PDA/eLambda Linearity Tester	
Installation Site: Flextronics Contract Manufacturing Site of WPPL in Singapore				
Purpose: To verify that supporting documentation is available prior to the completion of qualification.				
Test Execution: - List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header, then complete the table below. Rows may be added/removed as needed. - All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section.				
Objective Evidence:				
- Completed IQ-01 Test Script Data Sheet - SAP screenshots of below available document(s)				
Document Type	Title, Doc. #, Version/Revision #	Status in SAP	Initial & Date	
TSP	PDA Final Test - Test and Specification Procedure; 735001613; Version 22	Ready	H7 25 Jun 2019	
Comments: 				
Overall Test Conclusion		Document No.: <u>TE82969-1-IQR</u> Iteration No.: <u>03</u> Attachment: <u>7.3</u> Page: <u>1</u> of <u>1</u>		
☒ Pass ☐ Fail				

Title: *Installation Qualification Protocol*

Document # 730004135

Version # 02

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Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82969-1	Equipment Name:	PDA/eLambda Linearity Tester		
Installation Site: Flextronics Contract Manufacturing Site of WPPL in Singapore					
Purpose: To verify that the installed software/firmware is correct per the applicable design and/or operational document(s).					
Test Execution: - List all relevant Equipment software and/or instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed. - List the associated required equipment software and/or critical instrument/internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column. - Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below.					
Objective Evidence: - Completed IQ-04 Test Script Data Sheet - Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report. - Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable					
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Equipment Software	Version: 2.2	Version: 2.2	Pass	H2 25Jun2019	
Comments: <i>N/A</i> <i>JG</i> <i>25Jun 2019</i>					
Overall Test Conclusion			Document No.: <u>TE82969-1-IQR</u> Iteration No.: <u>03</u> Attachment: <u>7.4</u> Page: <u>1</u> of <u>1</u>		
☒ Pass ☐ Fail					

Test Script # IQ-06	IQ Test Name: Functional Verification		
Equipment # TE82969-1	Equipment Name: PDA/eLambda Linearity Tester		
Installation Site: Flextronics Contract Manufacturing Site of WPPL in Singapore			
Purpose: To verify that the system operates as expected.			
Test Execution: - Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835. - List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column. - Define the appropriate Acceptance Criteria within the Acceptance Criteria column. - Perform a test of the UUT(s), verify the Acceptance Criteria, then complete the table below. If an associated Test Record is being used as objective evidence the Header/Footer information should be verified for accuracy.			
Objective Evidence: - Completed IQ-06 Test Script Data Sheet - Copy of the Test Record(s) for the UUT(s), as applicable - The UUT(s) selected for this Test Script and the reasoning for why it/they were selected shall be summarized within the associated Installation Qualification Report. - If this Acceptance Criteria is other than "All required CTQ Specification measurements result in a Pass" then it shall be summarized within the associated VAF, Process Validation Plan, and/or Installation Qualification Report. - For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.			
UUT Part Number/Serial Number	Acceptance Criteria	Pass/Fail	Initial & Date
Part Number: 700012243 Serial Number: 22K6P003	The UUT Serial Number is correctly listed at the bottom of the Test Record.	Pass	HZ 25Jun2019
Part Number: 700012245 Serial Number: 22K4B002	The UUT Serial Number is correctly listed at the bottom of the Test Record.	Pass	HZ 25Jun2019
Comments: N/A <i>JE</i> 25Jun2019			
Overall Test Conclusion ☒ Pass ☐ Fail		Document No.: TE82969-1-IQR Iteration No.: 03 Attachment: 7.5 Page: 1 of 1	

Waters Corporation - Test Record

Part Number: 700012243

Product: 2998 Optics Bench On-Semi

Operator: 246154

Start Time: 06/14/2019, 10:02:

Serial Number: 22K6P003

End Time: 06/14/2019, 10:06:

Test System: TE82969-1

Order: N/A

Test Software: 2.2

Location: Flextronics, SG

TMD: N/A

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

Name	LSL	Measurement	USL	Unit	Outcome
%RSD	0	4.249	5		PASS
Mean		0.089			PASS
Std Dev		0.004			PASS
Lambda		257.06			PASS
A/C 5mg		0.0911			PASS
A/C 10mg		0.0903			PASS
A/C 15mg		0.0885			PASS
A/C 20mg		0.0914			PASS
A/C 25mg		0.089			PASS
A/C 30mg		0.0813			PASS

2998 Optics Bench Linearity Test Overall Result - PASS

Signed: 246154 

Date: 14 JUN 2019

END OF DATA

Document No.: TE82969-1-IQR
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Attachment: 7.6 Page: 1 of 2

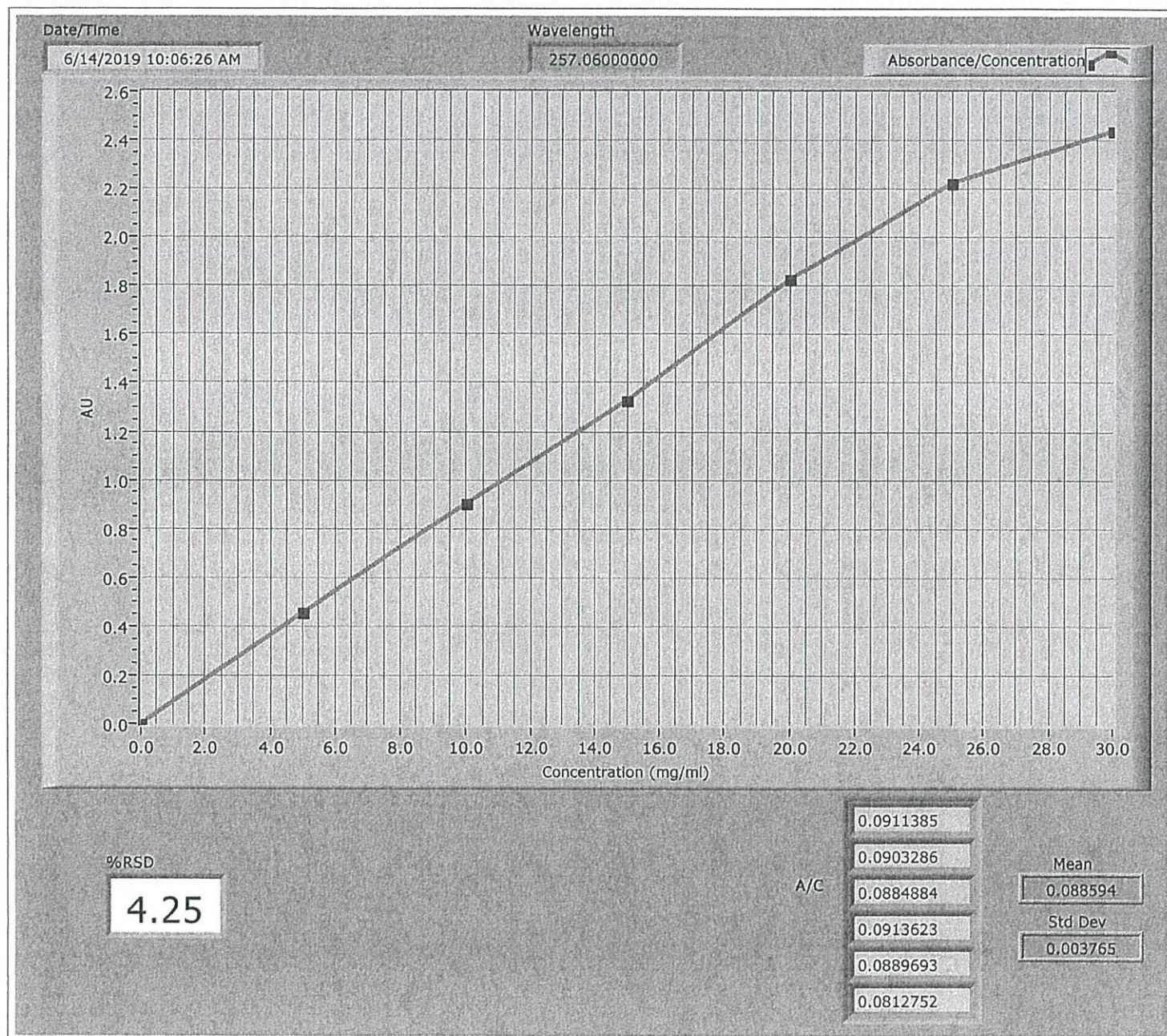


Linearity Graph

C:\Program Files\PDALin 2.2\PDA Linearity.exe\CrunchData.vi

Last modified on 6/14/2019 at 10:06 AM

Printed on 6/14/2019 at 10:06 AM



Document No.: TE8296A-1-IQR
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Attachment: 7.6 Page: 7 of 2

Waters Corporation - Test Record

Part Number: 700012245

Product: eLambda Optics Bench On-Semi

Operator: 246154

Start Time: 06/14/2019, 11:35:

Serial Number: 22K4B002

End Time: 06/14/2019, 11:44:

Test System: TE82969-1

Order: N/A

Test Software: 2.2

Location: Flextronics, SG

TMD: N/A

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

Name	LSL	Measurement	USL	Unit	Outcome
%RSD	0	4.803	5		PASS
Mean		0.09			PASS
Std Dev		0.004			PASS
Lambda		257.64			PASS
A/C 5mg		0.0931			PASS
A/C 10mg		0.0939			PASS
A/C 15mg		0.0909			PASS
A/C 20mg		0.0825			PASS
A/C 25mg		0.0921			PASS
A/C 30mg		0.0874			PASS

eLambda Optics Bench Linearity Test Overall Result - PASS

Signed: 246154 

Date: 14 JUN 2019

END OF DATA

Document No.: TE82969-1-I&R
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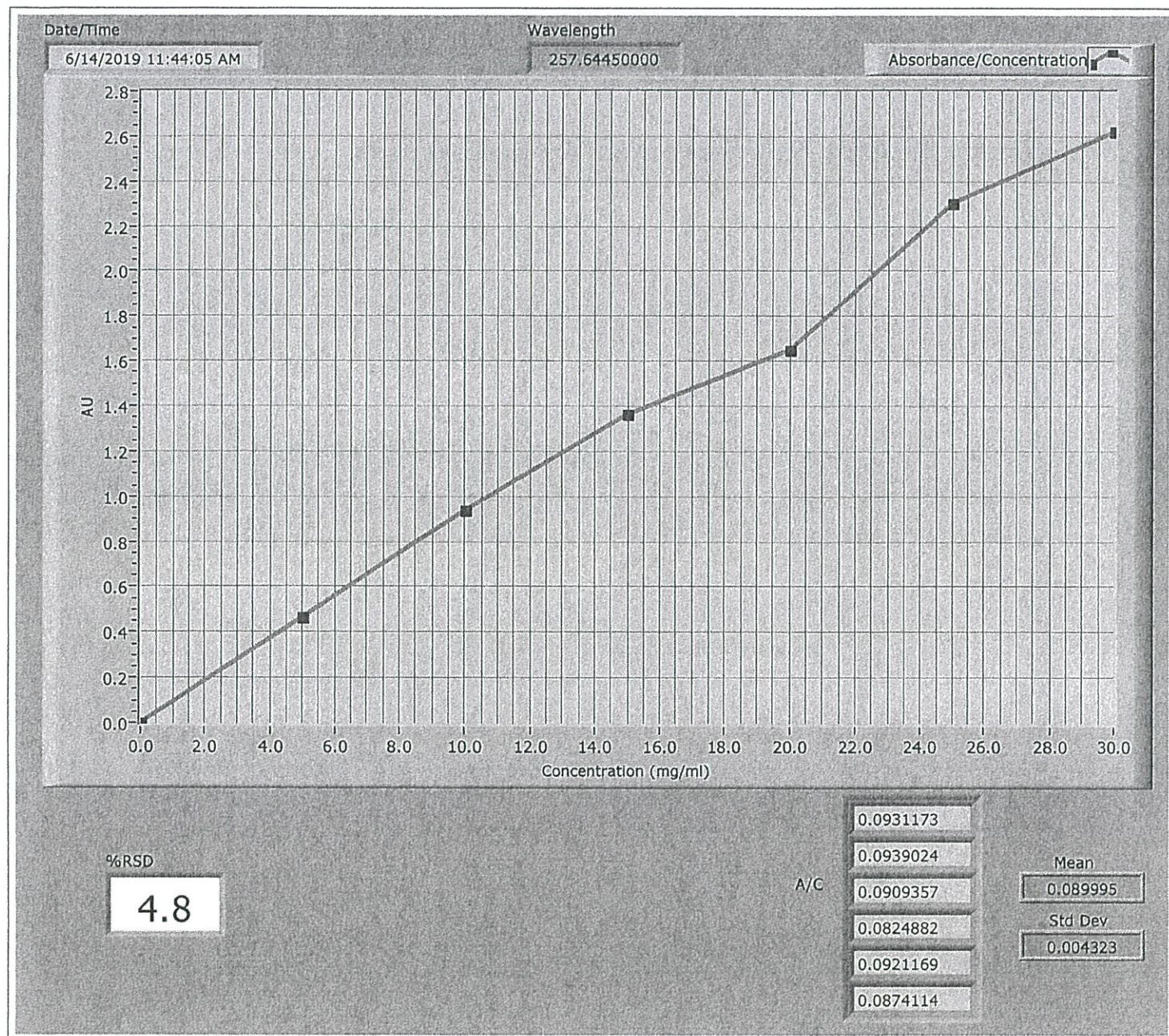


Linearity Graph

C:\Program Files\PDALin 2.2\PDA Linearity.exe\CrunchData.vi

Last modified on 6/14/2019 at 11:44 AM

Printed on 6/14/2019 at 11:44 AM



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