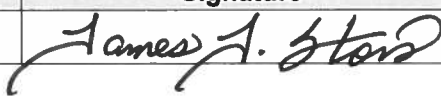


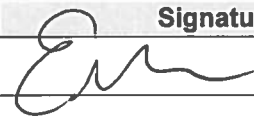
Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE82969-2-IQR	Iteration No: 01	SAP No: TE0082969QX	

INSTALLATION QUALIFICATION REPORT
For the PDA/eLambda Linearity Tester (TE82969-2)

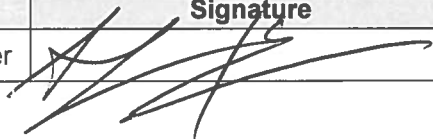
PREPARED BY

Name	Role	Signature	Date
James J. Stors	Senior Test Validation Engineer		21 FEB 2018

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principal Test Engineer		21 FEB 2018

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		22 Feb 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	New software version to add the 30mg concentration test.

 THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
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1.0 Purpose

The PDA/eLambda Linearity Tester, TE82969-2, is located in Warranty and Repair in Milford, MA. The PDA/eLambda Linearity Tester is used to perform and verify that linearity of PDA Detectors of the following part numbers are within specification: 186015026, 186002998, 186015032, 186015033, 186015030, 700002787, 700004035, 700005424, 700005427, 186299800, N2971013, N2971035, 186017003, 279002655, and 186017013; as well as the equivalent refurbished part numbers: 800000202, 800000244, 800000245, 800000304, 800000305, 800000397, 800000453, and 800000476. Note that not all part numbers have a refurbished equivalent. 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 (TE82969-2) based on the requirements of the performed Installation Qualification, 730004135, Version 00 as outlined by the Test Software Version 2.1 risk assessment, per TE82969-03JAN2018-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, 2.1, 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 system reports the 30mg concentration test, which is new for the 186015033, ACQUITY PDAe Detector, on the Test Record.

All other testing performed, as detailed in TE82969-2-IQR, Iteration 00, remains valid and applicable.

3.0 Summary of Results - Statement of Fitness for Intended Use

The PDA/eLambda Linearity Tester (TE82969-2) was tested in accordance with the applicable sections of the Installation Qualification Protocol, 730004135, Version 00, as outlined in the Test Software Version 2.1 risk assessment, per TE82969-03JAN2018-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 (TE82969-2) 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 (TE82969-2) remains fully qualified and fit for intended use post the change, as outlined in TE82969-03JAN2018-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 Engineer who performed the PDA/eLambda Linearity Tester (TE82969-2) Installation Qualification is the Author of the Installation Qualification Procedure, 730004135, Version 00, and is therefore trained.

The Engineer who performed the testing of the UUT using the PDA/eLambda Linearity Tester (TE82969-2) per Installation Qualification Procedure, 730004135, Version 00, IQ-06, Functional Verification test Script, is the author of the updated PDA Final Test System Test and Specification Procedure, 735001613, Version 20, and is therefore trained.

6.0 Qualification Results

6.1 Test Script IQ-01, Associated Documentation Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 00, for the PDA Final Test System Test and Specification Procedure, 735001613, as outlined in TE82969-03JAN2018-VAF.

6.1.1 IQ-01, Associated Documentation Verification Data Sheet, is provided as Attachment 7.1.

6.1.2 The updated PDA Final Test System Test and Specification Procedure, 735001613, Version 20, was confirmed to have been updated with software version 2.1 and to be in SAP with a status of Ready. A screen capture is provided below:

Document List After Selection 21 Hits											
											
Rev	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
	TSP	735001613	00	000	Acquity PDA Final Test	RELEASE GENERAL		06/25/2007	03/30/2008		Eric Turner
	TSP	735001613	01	000	Acquity PDA Final Test	ABANDON					Bruce Porter
B	TSP	735001613	02	000	Acquity PDA Final Test	RELEASE GENERAL		03/31/2008	05/11/2008	9134035	Eric Turner
C	TSP	735001613	03	000	Acquity PDA Final Test	RELEASE GENERAL		05/12/2008	07/09/2008	9134937	Eric Turner
D	TSP	735001613	04	000	PDA Final test	RELEASE GENERAL		07/10/2008	12/03/2008	9136327	Eric Turner
E	TSP	735001613	05	000	PDA Final test	RELEASE GENERAL		12/04/2008	03/29/2009	9139040	Eric Turner
F	TSP	735001613	06	000	PDA Final test	RELEASE GENERAL		03/30/2009	05/21/2009	9140911	Eric Turner
G	TSP	735001613	07	000	PDA Final test	RELEASE GENERAL		05/22/2009	07/01/2010	9142852	Eric Turner
H	TSP	735001613	08	000	PDA Final test	RELEASE GENERAL		07/02/2010	11/22/2010	9153554	Eric Turner
J	TSP	735001613	09	000	PDA Final test	RELEASE GENERAL		11/23/2010	07/04/2012	9157158	Chris Green
	TSP	735001613	10	000	PDA Final test	ABANDON					Eric Turner
K	TSP	735001613	11	000	PDA Final test	RELEASE GENERAL		07/05/2012	02/09/2014	9171410	Eric Turner
L	TSP	735001613	12	000	PDA Final test	RELEASE GENERAL		02/10/2014	02/18/2014	9185711	Chris Green
M	TSP	735001613	13	000	PDA Final test	RELEASE GENERAL		02/19/2014	10/12/2014	9186532	Eric Turner
N	TSP	735001613	14	000	PDA Final test	RELEASE GENERAL		10/13/2014	03/24/2015	9192039	Eric Turner
	TSP	735001613	15	000	PDA Final test	ABANDON					Eric Turner
P	TSP	735001613	16	000	PDA Final test	RELEASE GENERAL		03/25/2015	07/12/2015	9195587	Eric Turner
R	TSP	735001613	17	000	PDA Final test	RELEASE GENERAL		07/13/2015	12/10/2015	9198916	Eric Turner
T	TSP	735001613	18	000	PDA Final test	RELEASE GENERAL		12/11/2015	11/28/2017	9202728	Tyler Modelski
U	TSP	735001613	19	000	PDA Final test	RELEASE GENERAL		11/29/2017	12/31/9999	9218596	Eric Turner
	TSP	735001613	20	000	PDA Final test	READY					Eric Turner

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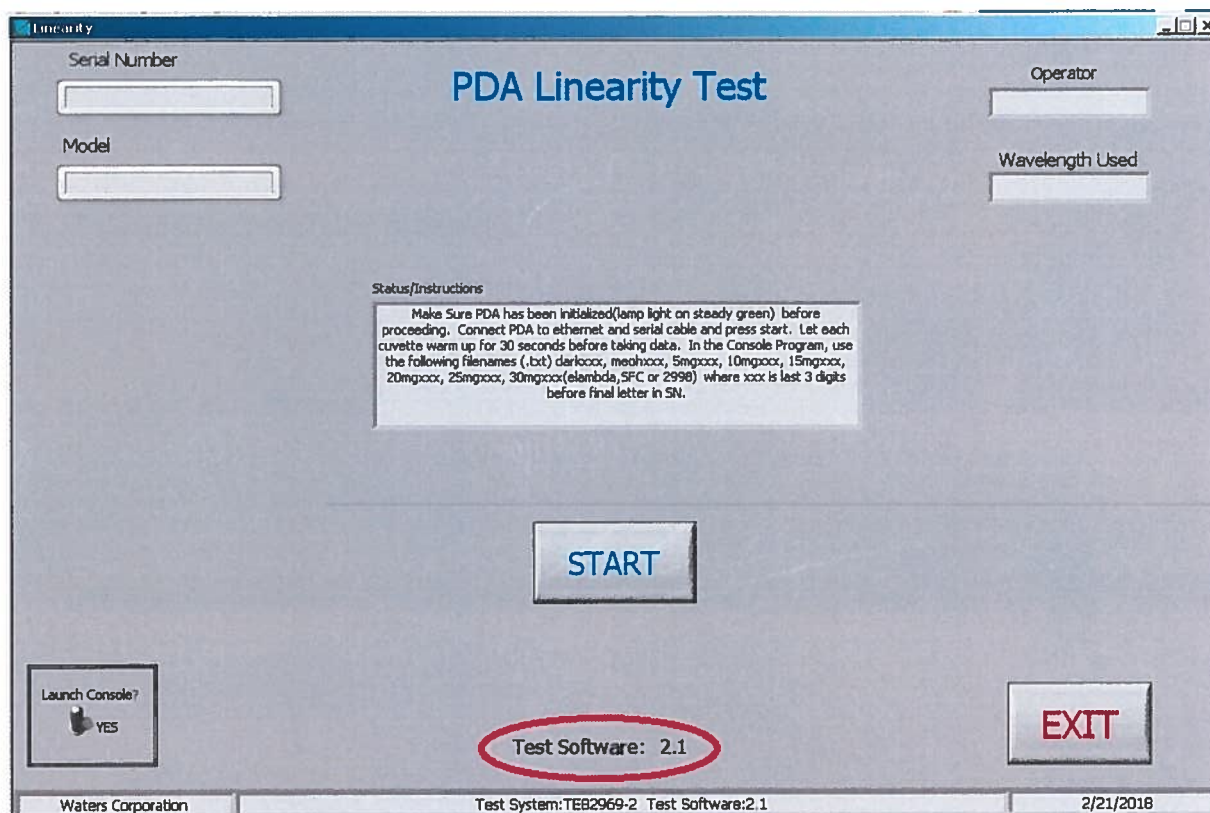
Iteration No: 01

SAP No: TE0082969QX

6.2 Test Script IQ-04, Test Software and Instrument Firmware Version, was performed in accordance with Installation Qualification Protocol, 730004135, Version 00, for the updated software version 2.1, as outlined in TE82969-03JAN2018-VAF.

6.2.1 IQ-04, Test Software and Instrument Firmware Version Data Sheet, is provided as Attachment 7.2.

6.2.2 The Test Equipment Software version listed in 735001613, PDA Final Test System Test and Specification Procedure (Version 20), is 2.1 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 00, for the updated software version 2.1, as outlined in TE82969-03JAN2018-VAF.

6.3.1 IQ-06, Functional Verification Data Sheet is provided as Attachment 7.3.

6.3.2 One (1) UUT, Part Number 186015033, as required by TE82969-03JAN2018-VAF, was tested using the TE82969-2, PDA/eLambda Linearity Tester, and met the requirement of running the 30mg concentration test and reporting it properly on the Test Record.

6.3.2.1 The Instrument Test Record is provided as Attachment 7.4.

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 7.1	None
IQ-04	Pass	Attachment 7.2	None
IQ-06	Pass	Attachment 7.3 and 7.4	None

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7.0 Attachments

- 7.1 IQ-01, Associated Documentation Verification Test Script Data Sheet
- 7.2 IQ-04, Test Software and Instrument Firmware Version Test Script Data Sheet
- 7.3 IQ-06, Functional Verification Test Script Data Sheet
- 7.4 Instrument Final Test Record for IQ-06, Part Number: 186015033, Serial Number: A18UPL015R

8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the Installation Qualification, 730004135, Version 00, for the PDA/eLambda Linearity Tester (TE82969-2), as outlined in the Test Software Version 2.1 risk assessment, per TE82969-03JAN2018-VAF.

9.0 References

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

Document Number	Document title
730004135, Version 00	Installation Qualification Protocol
TE82969-03JAN2018	Test Software Version 2.1 risk assessment
735001613 Version 20	PDA Final Test System Test and Specification Procedure

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test name: Associated Documentation Verification		Test Script No.: IQ-01	
Equipment No./ID: TE82969-2		Equipment Name: PDA/eLambda Linearity Tester	
Installation Site: Milford Warranty and Repair			
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 and then complete the table below. If applicable documents are unavailable state why in the comments section. All applicable documents must be in either Ready, Pre-Rel-Prod, or Release General state in SAP. Enter N/A for any parameter or cell that is not used or not applicable. Objective evidence: Completed Test Script Data Sheet SAP Screen shot of below available document(s)			
Document Type	Title; Doc. No.; Revision/Version No.	Status in SAP	Initial & Date
TSP	PDA Final Test - Test and Specification Procedure; 735001613; Version 20	READY	AB 21 FEB 2018
Comments: N/A James A. Stone 21 FEB 2018			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IOQ Test name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04	
Equipment No./ID: TE82969-2		Equipment Name: PDA/eLambda Linearity Tester		
Installation Site: Milford Warranty and Repair				
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: 2.1	Version: 2.1	PASS	AS 21 FEB 2018
Comments: N/A James J. Stone 21 FEB 2018				
Overall Test Conclusion: ☒ Pass ☐ Fail				

Copy this Test Script as needed

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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Copy this Test Script as needed

IOQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE82969-2		Equipment Name: PDA/eLambda Linearity Tester	
Installation Site: Milford Warranty and Repair			
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: 186015033 UUT Serial Number: A18UPL015R	30mg concentration test runs and is properly reported on the Test Record.	PASS	AS 21 FEB 2018
Comments: N/A James A. Store 21 FEB 2018			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Waters Corporation - Test Record

Part Number: 186015033

Product: eLambda PDA

Operator: USPLMEC54

Start Time: 02/21/2018, 13:48:33

Serial Number: A18UPL015R

End Time: 02/21/2018, 13:48:43

Test System: TE82969-2

Order: N/A

Test Software: 2.1

Location: Repair, Milford, US

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
%RSD	0	4.161	5		PASS
Mean		0.089			PASS
Std Dev		0.004			PASS
Lambda		257.15			PASS
A/C 5mg		0.0919			PASS
A/C 10mg		0.0924			PASS
A/C 15mg		0.0914			PASS
A/C 20mg		0.0901			PASS
A/C 25mg		0.0882			PASS
A/C 30mg		0.0825			PASS

eLambda PDA Linearity Test Overall Result - PASS

Signed: 

Date: 21 FEB 2018

END OF DATA

Document No.: TE82969-2-1QR
Iteration No.: 01
Attachment: 7.4 Page: 1 of 1