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

PREPARED BY

Name	Role	Signature	Date
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REVIEWED BY

Name	Role	Signature	Date
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APPROVED BY

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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.

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 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 (TE82969-1) based on the requirements of the performed Installation Qualification, 730004135, Version 02 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 TE82969-1-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 2.1 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 (TE82969-1) 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 TE82969-03JAN2018-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

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 20. 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 TE82969-03JAN2018-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 20, was confirmed to have been updated with software version 2.1 and to be in SAP with a status of Release General. A screen capture is provided below:

Document List After Selection ***22 Hits***

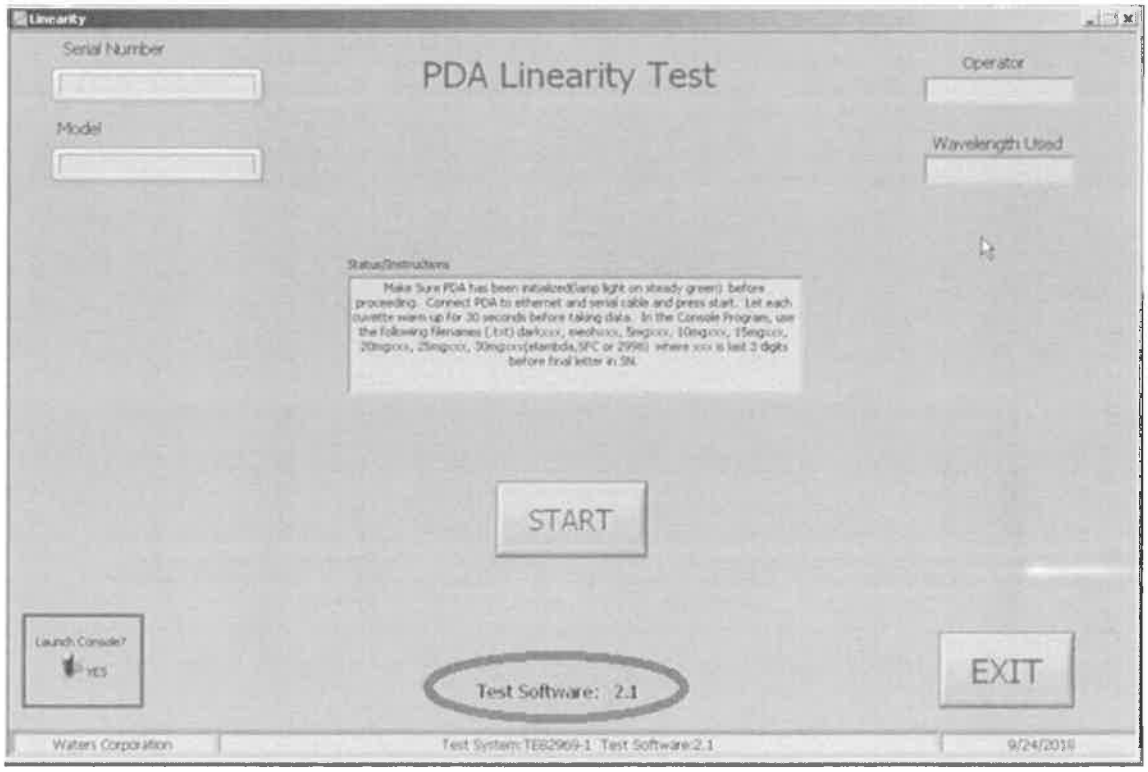
Choose Save Thumbnails (Images)

RevL	Ty.	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		25.06.2007	30.03.2008		Eric Turner
	TSP	735001613	01	000	Acquity PDA Final Test	ABANDON					Bruce Porter
B	TSP	735001613	02	000	Acquity PDA Final Test	RELEASE GENERAL		31.03.2008	11.05.2008	9134035	Eric Turner
C	TSP	735001613	03	000	Acquity PDA Final Test	RELEASE GENERAL		12.05.2008	09.07.2008	9134937	Eric Turner
D	TSP	735001613	04	000	PDA Final test	RELEASE GENERAL		10.07.2008	03.12.2008	9136327	Eric Turner
E	TSP	735001613	05	000	PDA Final test	RELEASE GENERAL		04.12.2008	29.03.2009	9139040	Eric Turner
F	TSP	735001613	06	000	PDA Final test	RELEASE GENERAL		30.03.2009	21.05.2009	9140911	Eric Turner
G	TSP	735001613	07	000	PDA Final test	RELEASE GENERAL		22.05.2009	01.07.2010	9142852	Eric Turner
H	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
	TSP	735001613	10	000	PDA Final test	ABANDON					Eric Turner
K	TSP	735001613	11	000	PDA Final test	RELEASE GENERAL		05.07.2012	09.02.2014	9171410	Eric Turner
L	TSP	735001613	12	000	PDA Final test	RELEASE GENERAL		10.02.2014	18.02.2014	9185711	Chris Green
M	TSP	735001613	13	000	PDA Final test	RELEASE GENERAL		19.02.2014	12.10.2014	9186532	Eric Turner
N	TSP	735001613	14	000	PDA Final test	RELEASE GENERAL		13.10.2014	24.03.2015	9192039	Eric Turner
	TSP	735001613	15	000	PDA Final test	ABANDON					Eric Turner
P	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	9198916	Eric Turner
T	TSP	735001613	18	000	PDA Final test	RELEASE GENERAL		11.12.2015	28.11.2017	9202728	Tyler Model
U	TSP	735001613	19	000	PDA Final test	RELEASE GENERAL		29.11.2017	09.09.2018	9218596	Eric Turner
V	TSP	735001613	20	000	PDA Final test	RELEASE GENERAL		10.09.2018	31.12.9999	9224731	Eric Turner
	TSP	735001613	21	000	PDA Final test	IN WORK					Eric Turner

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 2.1, as outlined in TE82969-03JAN2018-VAF.

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

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 02, 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 7.5.

6.3.2 One (1) UUT, Part Number 186015033, as required by TE82969-03JAN2018-VAF, was tested using the TE82969-1, 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 7.6.

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 and 7.6	None

7.0 Attachments

7.1 Completed Executor Training Record 730004135, Ver.02

7.2 Completed Operator Training Record 735001613, Ver.20

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 Instrument Final Test Record for IQ-06, Part Number: 186015033, Serial Number: J18UPL246A

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 2.1 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 02	Installation Qualification Protocol
TE82969-03JAN2018	Test Software Version 2.1 risk assessment
735001613 Version 20	PDA Final Test System Test and Specification Procedure

Appendix A: TRAINING RECORD

Document #	735004135	Document Title	Installation Qualification Protocol	Version	02
				Revision	N/A

Training Performed By: (If not used this section can be deleted)

SELF		06 Aug 2018
Printed Name	Signature	Date

☑ Read and Understood (If self-trained – If not self-trained this section can be deleted)

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
LUO HUAZHENG		HZ	06 Aug 2018

N/A 06 Aug 2018

Print multiple copies of this Training Record Template as needed

Document No.: TE 82969-1-IQR
Iteration No.: 02
Attachment: 7.1 Page: 1 of 1

Appendix A: TRAINING RECORD

Document #	735001613	Document Title	PDA Final Test System Test and Specification Procedure	Version	20
				Revision	U

Training Performed By: (If not used this section can be deleted)

SELF	N/A	26 SEP 2018
Printed Name	Signature	Date

☑ Read and Understood (If self-trained – If not self-trained this section can be deleted)

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 MAMALATED DEDUYO		JMD	25 SEP 2018
AU WENG ONN		AWO	25 SEP 2018
KWEK CHOCK MENG		KCM	25 SEP 2018
	N/A		
			25 SEP 2018

Print multiple copies of this Training Record Template as needed

Document No.: TE82969-1-IQR
Iteration No.: 02
Attachment: 7.2 Page: 1 of 1

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 20	RELEASE GENERAL	HZ 26 SEP 2018

Comments:

N/A JC 26 SEP 2018

Overall Test Conclusion	
☒ Pass	☐ Fail

Document No.: TE82969-1-IQR
Iteration No.: 02
Attachment: 7.3 Page: 1 of 1

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
Test Equipment Software	Version: 2.1	Version: 2.1	PASS	HZ 26 SEP 2018

Comments:

N/A JE 26 SEP 2018

Overall Test Conclusion	
☒ Pass ☐ Fail	Document No.: TE82969-1-IQR Iteration No.: 02 Attachment: 7.4 Page: 1 of 1

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
UUT Part Number: 186015033 **UUT Serial Number:** J18UPL246A	30mg concentration test runs and is properly reported on the Test Record.	PASS	HZ 26 SEP 2018

Comments:
N/A JB 26SEP2018

Overall Test Conclusion	
☒ Pass ☐ Fail	Document No.: TE82969-1-IQR Iteration No.: 02 Attachment: 7.5 Page: 1 of 1

Waters Corporation - Test Record

Part Number: 186015033	Product: eLambda PDA
Operator: 842185	Start Time: 09/25/2018, 17:30:
Serial Number: J18UPL246A	End Time: 09/25/2018, 17:32:
Test System: TE82969-1	Order: NA
Test Software: 2.1	Location: Flextronics,SG

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

Name	LSL	Measurement	USL	Unit	Outcome
%RSD	0	4.263	5		PASS
Mean		0.09			PASS
Std Dev		0.004			PASS
Lambda		257.6			PASS
A/C 5mg		0.0929			PASS
A/C 10mg		0.0932			PASS
A/C 15mg		0.0933			PASS
A/C 20mg		0.0906			PASS
A/C 25mg		0.0875			PASS
A/C 30mg		0.0838			PASS

eLambda PDA Linearity Test Overall Result - PASS

Signed: 842185	Date: 25 SEp 2018

END OF DATA

Document No.: TE82969-1-IQR
Iteration No.: 02
Attachment: 7.6 Page: 1 of 1