

INSTALLATION QUALIFICATION REPORT

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

PREPARED BY

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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
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

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Iteration No: 02

SAP No: TE0082969QX

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 Ready. 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

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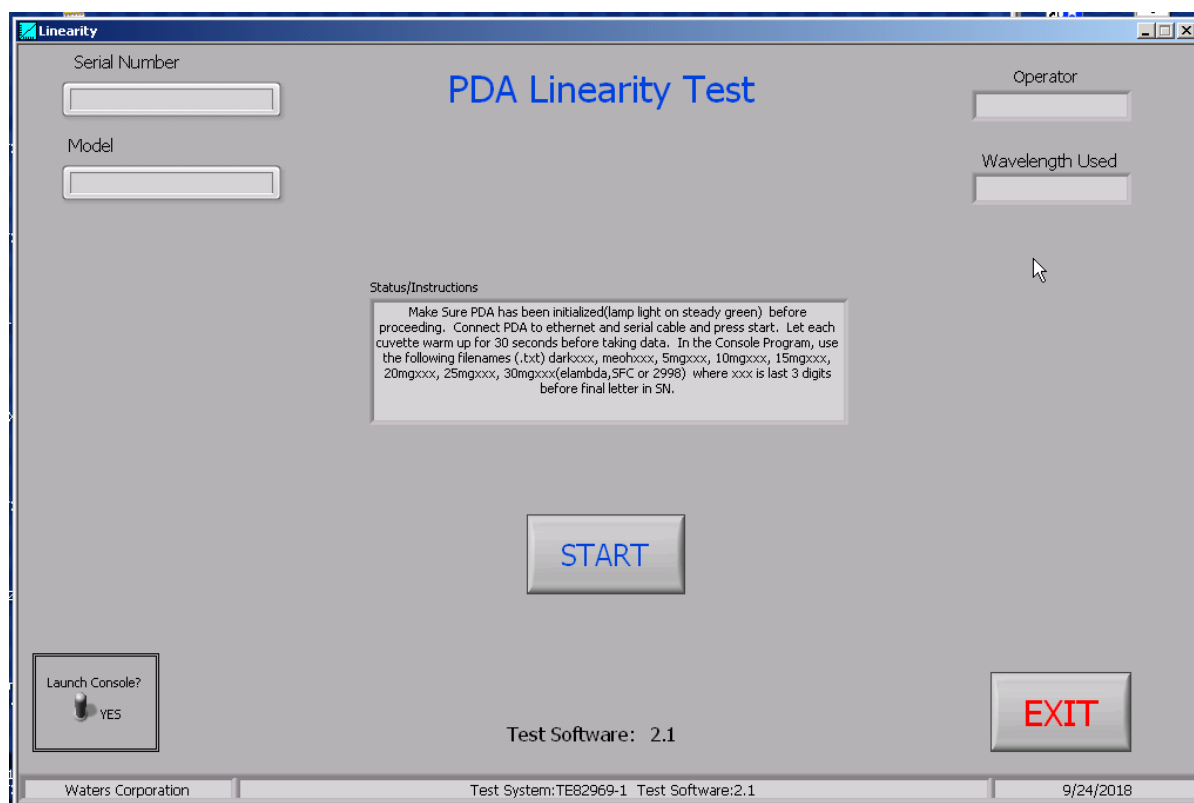
Iteration No: 02

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 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

Template 730002845, Version 02

Ref. 730001835, Process Validation Procedure for Milford Site

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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