

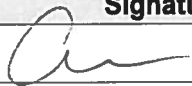
Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE82969-1-IQR	Iteration No: 00	SAP No: TE0082969QX	

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

PREPARED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		23 Oct 2017

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principal Test Engineer		24 OCT 2017

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		14 Nov 2017

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

1.0 Purpose

The PDA / eLambda Linearity Tester (TE82969-1) is located in the Flextronics Contractor Manufacturer site in Singapore. This station is used to verify that linearity of PDA Detectors of the following part numbers is within specification: 186015026, 186002998, 186015032, 186015033, 186015030, 700002787, 700004035, 700005424, 700005427, 186299800, N2971013, N2971035, 186020003, 186017003, 279002655, and 186017013. 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.

This Installation Qualification is being performed as required by the Validation Assessment Form TE82969-28SEP17-VAF which 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 PDA / eLambda Linearity Tester (TE82969-1) based on the requirements of the Installation Qualification Procedure 730004135, Ver. 00 and TE82969-28SEP17-VAF.

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

3.0 Summary of Results - Statement of Fitness for Intended Use

The PDA / eLambda Linearity Tester was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 00 and TE82969-28SEP17-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 complies 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) can be considered fully qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
BOM	Bill of Materials
CAL/PM	Calibration/Preventive Maintenance
cGMP	Current Good Manufacturing Practice
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
VAF	Validation Assessment Form

Report No: TE82969-1-IQR

Iteration No: 00

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5.0 Training

The operator of the PDA / eLambda Linearity Tester (TE82969-1) was the author of the PDA Final Test Procedure 735001613, Ver. 19 used for IQ-06: Functional Test and is considered trained. A training record of other site operators is provided as Attachment 7.1. The executors of this qualification were trained according to the Installation Qualification Procedure 730004135, Ver. 00. This training record is provided as Attachment 7.2.

6.0 Qualification Results

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The PDA Final Test Procedure 735001613, Ver. 19 was confirmed to be in SAP with a status of Ready, as evidenced below:

Document List After Selection

20 Hits

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Choose Save Thumbnails (Images)

Rev/Lev	Type	Document	Vs	Part	Description	Status text	Valid From	Change Number	Long name
	TSP	735001613	00	000	Acquity PDA Final Test	RELEASE GENERAL	06/25/2007		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	9134035	Eric Turner
C	TSP	735001613	03	000	Acquity PDA Final Test	RELEASE GENERAL	05/12/2008	9134937	Eric Turner
D	TSP	735001613	04	000	PDA Final test	RELEASE GENERAL	07/10/2008	9136327	Eric Turner
E	TSP	735001613	05	000	PDA Final test	RELEASE GENERAL	12/04/2008	9139040	Eric Turner
F	TSP	735001613	06	000	PDA Final test	RELEASE GENERAL	03/30/2009	9140911	Eric Turner
G	TSP	735001613	07	000	PDA Final test	RELEASE GENERAL	05/22/2009	9142852	Eric Turner
H	TSP	735001613	08	000	PDA Final test	RELEASE GENERAL	07/02/2010	9153554	Eric Turner
J	TSP	735001613	09	000	PDA Final test	RELEASE GENERAL	11/23/2010	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	9171410	Eric Turner
L	TSP	735001613	12	000	PDA Final test	RELEASE GENERAL	02/10/2014	9185711	Chris Green
M	TSP	735001613	13	000	PDA Final test	RELEASE GENERAL	02/19/2014	9186532	Eric Turner
N	TSP	735001613	14	000	PDA Final test	RELEASE GENERAL	10/13/2014	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	9195587	Eric Turner
R	TSP	735001613	17	000	PDA Final test	RELEASE GENERAL	07/13/2015	9198916	Eric Turner
T	TSP	735001613	18	000	PDA Final test	RELEASE GENERAL	12/11/2015	9202728	Tyler Modelski
	TSP	735001613	19	000	PDA Final test	READY			Eric Turner

6.1.2 The PDA Linearity Test System Preventative Maintenance Procedure 735003437, Ver. 00 was confirmed to be in SAP with a status of Release General, as evidenced below:

Document List After Selection						1 Hits		Waters	
              Choose  Save       Thumbnails (Images)									
Rev/Lev	Type	Document	Vs	Part	Description	Status text	Valid From	Change Number	Long name
A	CAL	735003437	00	000	PDA Linearity Test System PM	RELEASE GENERAL	10/24/2014	9192486	Enc Turner

6.2 Test Script IQ-02: Site Verification and Test Script IQ-03: Instrumentation Calibration Verification were not performed according to TE82969-28SEP17-VAF.

6.3 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 7.4.

6.3.1 The TE82969 Test Equipment Software version listed in PDA Final Test Procedure 735001613, Ver. 19 is Test Software 2.0 and was verified to match the version listed on the Test Record. The Test Record is provided as Attachment 7.7.

6.3.2 The firmware version listed in the BOM for P/N: 186017013 is 1.65.6205 and was verified to match the version listed on the Test Record. A screen capture of the BOM in SAP is provided as Attachment 7.5. Refer to Attachment 7.7 for the Test Record.

Report No: TE82969-1-IQR

Iteration No: 00

SAP No: TE0082969QX

- 6.4 Test Script IQ-05: General Safety and Alarms was not performed according to TE82969-28SEP17-VAF.
- 6.5 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.
- 6.5.1 The Acquity Arc Bio PDA 2998 (P/N: 186017013) was chosen as the UUT for this Installation Qualification because it is the part number being added to the test system as specified in TE82969-28SEP17-VAF.
- 6.5.2 One (1) UUT (P/N: 186017013, S/N: K17UPD100A) was tested using the PDA / eLambda Linearity Tester (TE82969-1) with all tests passing. Refer to Attachment 7.7 for the passing Test Record.
- 6.6 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-01	Pass	Attachment 7.3	None
IQ-04	Pass	Attachments 7.4, and 7.5	None
IQ-06	Pass	Attachments 7.6 and 7.7	None

7.0 Attachments

- 7.1 Completed Operator Training Record 735001613, Ver. 19
- 7.2 Completed Executor Training Record 730004135, Ver. 00
- 7.3 Completed Test Script IQ-01: Associated Document Verification
- 7.4 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.5 Objective Evidence IQ-04: Screen Capture of the BOM for P/N: 186017013
- 7.6 Completed Test Script IQ-06: Functional Verification of UUT Part #186017013 (K17UPD100A)
- 7.7 Objective Evidence IQ-06: Passing Test Record for UUT Part #186017013 (K17UPD100A)

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
735001613, Ver. 19	PDA Final Test Procedure
735003437, Ver. 00	PDA Linearity Test System PM Procedure
721007611, Ver. 01	2998 PDA Detector Functional Specification
TE0082969QX	Validation Assessment Form TE82969-28SEP17-VAF

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WORK INSTRUCTION / OPERATING PROCEDURE

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

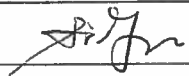
Page 10 of 11

Appendix A: TRAINING RECORD

Document No. 735001613 Procedure Title PDA Final Test Procedure Version 19

Training by: SELF N/A N/A
Printed name Signature Date

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 MANUELATO DEDUYO		JMD	17 09 2017
YEAP SIEW YEE		YSY	17 02 2017
N/A EEP 23 OCT 2017			

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Template 730000483 V06

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7.2
Attachment 7-Entry error YSP 19 Oct 17
Doc No: 7E82969-1-1QR
page 01 of 01 entry error
02 SEP 23 Oct 2017

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WORK INSTRUCTION / OPERATING PROCEDURE

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

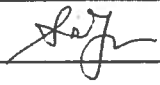
Page 10 of 11

Appendix A: TRAINING RECORD

Document No. 730004135 Procedure Title Installation Qualification Procedure Version 00

Training by: SELF N/A N/A
Printed name Signature Date

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
Yung Snow Yee		YSY	16 Oct 17
N/A SEP 23 Oct 2017			

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Type	Syllabus ID	Syllabus	Course ID	Course	Attended	Freq	Expires	Score	Status
Requirement	MILTESTENG	Test Engineering	730001834-VER-03	Test Engineering Management Policy	6/9/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730001834-VER-02	New Test Equipment Development Procedure	6/12/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730001835-VER-05	Process Validation Procedure for Milford	6/9/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730001836-VER-01	Sustaining Test Equipment Procedure	6/13/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730001936-VER-03	Test Method Validation Protocol	6/14/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730002232-VER-03	Process Validation Master Plan - Milford	6/14/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730002738-VER-00	New Product Intro Process - Milford (WIDP)	6/14/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730004135-VER-00	Installation Qualification Protocol	6/13/2017	0			Completed
Requirement	MILMFGOPSALL	All Milford Manufacturing & Support Personnel	EHS0000-VER-02	EHS Policies	6/6/2017	12	6/6/2018		Completed
Requirement	MILMFGOPSALL	All Milford Manufacturing & Support Personnel	LCDHR01-REV-01	Sexual Harassment Policy	6/9/2017	12	6/9/2018		Completed
Requirement	MILMFGOPSALL	All Milford Manufacturing & Support Personnel	QA0002-REV-01	Good Manufacturing Practices	6/12/2017	0			Completed
Requirement	MILMFGOPSALL	All Milford Manufacturing & Support Personnel	QA0008-REV-01	Quality Management Systems	6/13/2017	0			Completed

Version 00
 Document No.: TE82969-1-1QR
 Attachment: 7.2 Page: 2 of 2

Attachment 7.3
Doc No: TE82969-1-IQR
Page 01 of 01

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WORK INSTRUCTION / OPERATING PROCEDURE

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 4 of 11

IQ Test name: Associated Documentation Verification		Test Script No.: IQ-01	
Equipment No./ID: TE82969-1		Equipment Name: PDA/eLambda Linearity Tester	
Installation Site: Flextronics : 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 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 Procedure 7350011613, Ver. 19	Ready	Ysy 17 Oct 2017
CAL	PDA Linearity Test System PM 735003437, Ver. 00 Procedure	Release General	Ysy 17 Oct 2017
N/A ELP 13 Oct 2017			
N/A ELP 13 Oct 2017			
N/A ELP 13 Oct 2017			
N/A ELP 13 Oct 2017			
N/A ELP 13 Oct 2017			
N/A ELP 13 Oct 2017			
N/A ELP 13 Oct 2017			
Comments: N/A ELP 13 Oct 2017			
Overall Test Conclusion: ☒ Pass ☐ Fail			

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Attachment 7.4
 Doc No.: TE82969-1-1QR
 page 01 of 01

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Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 7 of 11

IOQ Test name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04	
Equipment No./ID: TE82864-1 ^{entry error YSY 17 Oct 2017} TE82969-1		Equipment Name: PDA/eLambda Linearity Tester		
Installation Site: Flextronics : 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
Test Equipment Software	Version: 2.0	Version: 2.00	Pass	YSY 19 Oct 2017
Instrument Firmware	Version: 1.65.6205	Version: 1.65.62050	Pass	YSY 19 Oct 2017
	Version:	Version:		
	Version: N/A EEP	Version:		
	Version:	Version:		
	Version:	Version: 13 Oct 2017		
	Version:	Version:		
	Version:	Version:		
Comments: Software version specified in 735001613, ver. 19 Firmware version specified in BOM for P/N: 186017013 EEP 13 Oct 2017 ① Refer to Attachment 7.7 for test record. Test software and instrument firmware are verified to be 2.0 and 1.65.6205. YSY 19 Oct 2017				
Overall Test Conclusion: ☒ Pass ☐ Fail				

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Display material BOM: General Item Overview

Waters
Full Site of www.waters.com

Material 188017013 ACQUITY Arc Bio 2998 PDA Detector

Plant US31 Manufacturing Milford, US

Alternative BOM 1

Validity

Header

New Entries

Subitems

Material Document General

Item	Kit	Component	Component description	Quantity	Un	A...	Sls	Valid From	V
0010	L	200000448	S/U Kit, ACQ Arc, 2998/2489/2475	1	EA	☒	☐	07/25/2017 1	1
0020	L	279003755	ASSEMBLY, DETECTOR 2998 ARC BIO	1	EA	☒	☐	07/25/2017 1	1
0030	L	280000695	BOX, SHIPPING, DETECTOR, 2998 LG	1	EA	☐	☐	07/25/2017 1	1
0040	L	361000593	ACQ Arc 2998 PDA Det F/W v1.65.6205	1	EA	☐	☐	07/25/2017 1	1
0050	L	716004592	Info, Set, ACQ, Arc & 2998 PDA Detector	1	EA	☒	☐	07/25/2017 1	1
0060	L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	07/25/2017 1	1
0070	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	☐	07/25/2017 1	1
0080	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☐	☐	07/25/2017 1	1
0090	L	WAT027033	CABLE TIE MINIATURE	1	EA	☐	☐	07/25/2017 1	1
0100	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	1	EA	☐	☐	07/25/2017 1	1
0110	L	WAT089533	BAG, POLY 2ML	1	EA	☐	☐	07/25/2017 1	1

Iteration 00
Document No.: TE82969-1-1QR
Attachment: 7.5 Page: 1 of 1

Attachment 7.6

Doc No: TE82969-1-1012

page 01 of 01

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WORK INSTRUCTION / OPERATING PROCEDURE

Title: Installation Qualification Procedure

Document No: 730004135

Version No. 00

Page 9 of 11

IOQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE82969-1		Equipment Name: PDA/Lambda Linearty Tester	
Installation Site: Flextronics: 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: 186017013 UUT Serial Number: K170PD100A	All required CTQ Specification measurements result in a Pass.	Pass	YSY 19022017
Comments: Refer to Attachment 7.7 for Test Record YSY 19022017			
Overall Test Conclusion: ☒ Pass ☐ Fail			

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Waters Corporation - Test Record

Part Number: 186017013

Product: Acquity Arc Bio PDA

Operator: USPLMEC54

Start Time: 10/19/2017, 14:13:

Serial Number: K17UPD100A

End Time: 10/19/2017, 14:13:

Test System: TE82969-1

Order: N/A

Test Software: 2.0

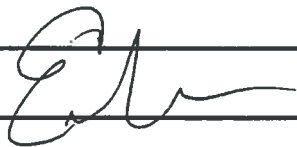
Location: Flextronics,SG

Firmware: 1.65 Build#: 6205 (Apr 03 2015)

Name	LSL	Measurement	USL	Unit	Outcome
%RSD	0	3.115	5		PASS
Mean		0.09			PASS
Std Dev		0.003			PASS
Lambda		257.01			PASS
A/C 5mg		0.0938			PASS
A/C 10mg		0.0911			PASS
A/C 15mg		0.0914			PASS
A/C 20mg		0.091			PASS
A/C 25mg		0.088			PASS
A/C 30mg		0.0859			PASS

Acquity Arc Bio 2998 PDA Linearity Test Overall Result - PASS

Signed:



Date: 19-OCT-2017

END OF DATA