

Appendix A: TRAINING RECORD

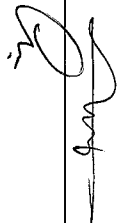
Document #	735001613	Document Title	PDA Final Test System Test and Specification Procedure	Version	20
Revision	U				

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

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 MAMALATEDO		JMD	25 SEP 2018
AU WENG O KH		AUO	25 SEP 2018
KUJEK CHOCOL MENUS		KCM	25 SEP 2018
N/A 25 SEP 2018			

Print multiple copies of this Training Record Template as needed

Document No.: _____
 Iteration No.: _____
 Attachment: _____ of _____

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.
 HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification
Equipment #	TE82969-1	Equipment Name:	PDA/Lambda 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	J M D 25 SEP 2018

Comments:

N/A

25 SEP 2018

Overall Test Conclusion		Document No.: _____
☒ Pass	☐ Fail	Iteration No.: _____
		Attachment: _____ Page: ____ of ____

Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version
Equipment #	TE82969-1	Equipment Name:	PDA/Lambda Linearity Tester
Installation Site:	Electronics Contract Manufacturing Site of WPPPL 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	JMO 25 SEP 2018

Comments:

N/A

[Signature] 25 SEP 2018

Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____
☒ Pass	☐ Fail	

Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE82969-1	Equipment Name:	PDA/Lambda 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	30mg concentration test runs and is properly reported on the Test Record.	PASS	JMD 25 SEP 2018	
UUT Serial Number:				
Comments: N/A <i>[Signature]</i> 25 SEP 2018				
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☒ Pass ☐ Fail				

Waters Corporation - Test Record

Part Number: 186015033
Operator: 842185
Serial Number: J18UPL246A
Test System: TE82969-1
Test Software: 2.1

Product: elambda PDA
Start Time: 09/25/2018, 17:30:
End Time: 09/25/2018, 17:32:
Order: NA
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: J 842185 Date: 25 Sep 2018

END OF DATA