

INSTALLATION QUALIFICATION REPORT For the PDA Detector Download Station (TE83057-4)

PREPARED BY

Name	Role	Signature	Date
Edwin Koh	Senior Operations Manager		24 AUG 2020

The "Prepared By" signature denotes that this document accurately describes the qualification activities.

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principal Test Engineer		

The "Reviewed By" signature[s] denotes agreement with the description of the qualification activities.

APPROVED BY

Name	Role	Signature	Date
Tan Kah Chin	Senior Quality Assurance Manager		

The "Approved By" signature denotes that this document has been reviewed and approved for overall quality and completeness.

Version:	00	Originator:	Edwin Koh	Change ID:	9236204
Summary of Change: Test Firmware Download for new PDA Premier					

REVISION HISTORY

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of 730004135, Installation Qualification Protocol, for the TE83057-4, PDA Detector Download Station.

SYSTEM BACKGROUND

The TE83057-4, PDA Detector Download Station, is located at Flex Pte Ltd, Singapore. The station is used to download instrument firmware to the following part numbers; 186015026, 186002998, 186015032, 186015033, 186015030, 700004035, 700004024, 700005027, 186299800, N2971013, N2971035, 186020003, 186017003, 279002655, 186017013 and 186018007.

The system is equipped with a PC running customer test program and the appropriate cables to connect the UUT. After the UUT is connected, the Operator selects the version on the test software program display and begin download. After the UUT has completed the firmware download according to the corresponding procedure, it is moved to the PDA Final Test System (TE82882) to undergo Final Test.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE83057-4, PDA Detector Download Station, based on the requirements of the executed protocol, 730004135, Installation Qualification Protocol, Version 03 as detailed in TE83057-07AUG2020-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE83057-4, PDA Detector Download Station was tested in accordance with the applicable sections of 730004135, Installation Qualification Protocol, Version 03 per TE83057-07AUG2020-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 TE83057-4, PDA Detector Download Station remains compliant with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE83057-4, PDA Detector Download Station remains fully qualified and fit for intended use.

4.0 ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
PDA	Photodiode Detector Array
cGMP	Current Good Manufacturing Practice
CTQ	Critical to Quality
IQR	Installation Qualification Report
N/A	Not Applicable
NPI	New Product Introduction
P/N	Part Number
SAP	Enterprise Resource Planning Software
TSP	Test Specification and Procedure
UUT	Unit Under Test
VAF	Validation Assessment Form

5.0 TRAINING

The executor of this qualification was trained to the Installation Qualification Protocol, 730004135, Version 03, and the training record is provided as Attachment 7.1

The Operator who performed the testing of the UUT using the TE83057-4, PDA Detector Download Station was trained to 735001613, ACQUITY PDA Final Instrument Test and Specification Procedure, Version 25 Rev AB and a Training Record is provided as Attachment 7.2

6.0 QUALIFICATION RESULTS

6.1 Test Script IQ-01, Associated Documentation Verification

Test Script IQ-01, Associated Documentation Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 03, and per TE83057-07AUG2020-VAF.

6.1.1 IQ-01, Associated Documentation Verification Test Script Data Sheet is provided as Attachment 7.3.

6.1.2 The 735001613, PDA Final Test and Specification Procedure, Version 25, was confirmed to be in SAP with a status of Ready. A screen capture is provided below:

Rev	Rev Lev	Type	Document	Vs	Part	Description	Status text	Current Ver	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 Modelski
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	06.12.2018	9224731	Eric Turner
W		TSP	735001613	21	000	PDA Final test	RELEASE GENERAL		07.12.2018	23.07.2019	9226454	Eric Turner
Y		TSP	735001613	22	000	PDA Final test	RELEASE GENERAL		24.07.2019	23.03.2020	9230015	Eric Turner
		TSP	735001613	23	000	PDA Final test	ABANDON					Eric Turner
AA		TSP	735001613	24	000	PDA Final test	RELEASE GENERAL		24.03.2020	31.12.9999	9234775	Eric Turner
		TSP	735001613	25	000	PDA Final test	READY					Eric Turner

6.1.3 All other system related documents were previously verified as assessed and were not affected by the changes summarized in TE83057-07AUG2020-VAF

6.2 TEST SCRIPT IQ-02, SITE VERIFICATION

Test Script IQ-02, Site Verification, was not performed as it was previously executed, and was not affected by the change summarized in TE83057-4 TE83057-07AUG2020-VAF

6.3 TEST SCRIPT IQ-03, INSTRUMENTATION CALIBRATION VERIFICATION

Test Script IQ-03, Instrumentation Calibration verification, was not performed as it was previously executed, and was not affected by the change summarized in TE83057-4 TE83057-07AUG2020-VAF

6.4 TEST SCRIPT IQ-04, SOFTWARE AND INSTRUMENT FIRMWARE VERSION

Test Script IQ-04, Software and Instrument Firmware version, was not performed as it was previously executed, and was not affected by the change summarized in TE83057-4 TE83057-07AUG2020-VAF

6.5 TEST SCRIPT IQ-05, GENERAL SAFETY AND ALARMS

Test Script IQ-05, General Safety and Alarms, was not performed as it was previously executed, and was not

affected by the change summarized in TE83057-4 TE83057-07AUG2020-VAF

6.6 TEST SCRIPT IQ-06, FUNCTIONAL VERIFICATION

Test Script IQ-06, Functional Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 03, for the updated software version 2.2, as outlined in TE83057-07AUG2020-VAF.

6.6.1 IQ-06, Software and Instrument Firmware Version Test Script Data Sheet is provided as Attachment 7.4

6.6.2 One (1) UUT, 186018007, ACQUITY Premier eLambda PDA, H20PPD001A, was selected for the Functional Verification UUT as the change summarized in TE83057-07AUG2020-VAF and met the requirement of functionality test and report properly on test record.

6.2.2.1 The instrument Test Record is provided as attachment 7.5

6.6.3 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-06	Pass	Attachment 7.4 and 7.5	None

7.0 ATTACHMENTS

7.1 Completed Executor Training Records 730004135, Ver 03

7.2 Completed Operator Training Records 735001613, Ver 25

7.3 IQ-01 – Associated Documentation Verification Test Script Data Sheet

7.4 IQ-06 – Functional Verification Test Script Data Sheet

7.5 Instrument Final Test Record for Test Script IQ-06, Part number 186018007, serial number: H20PPD001A

8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution the 730004135, Installation Qualification Procedure, Version 03, for TE83057-4, PDA Detector Download Station.

9.0 REFERENCES

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

Document Number	Document title
730004135, Version 03	Installation Qualification Protocol
735001613, Version 25	PDA Final Instrument Test and Specification Procedure
TE83057-07AUG2020-VAF	TE83057-04 PDA Detector Download Station Validation Assessment Form
ECO9236204	Engineering Change Request to release the Acquity Premier eLambda PDA

Title: Individual Training Form

Document No: 730002657

Version No: 01

Page 1 of 1

Training Type:	Read and Understood		
Name:	Edwin Koh	Employee ID:	617859
Date of Training:	16 Aug 2020		
Comments:	N/A		

Document Number	Title	Rev #
730004135	Installation Qualification Protocol	03
N/A <i>Edwin Koh</i> 24 AUG 2020		

 Employee's Signature	Senior Operations Manager Title	24 AUG 2020 Date

Document No.: TE83057-4-IQR
 Iteration No.: 00
 Attachment: 7.1 Page 1 of 1

Appendix A: TRAINING RECORD

Document #	735001613	Document Title	PDA Final Instrument TSP	Version	25
				Revision	AB

☒ 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 MAMALATEO DEDUYO		JMD	17 Aug 2020
CHAI CHUAN WEI		CCW	17 Aug 2020
HO TECK LIK		HTL	17 Aug 2020

Print multiple copies of this Training Record Template as needed

Document No.: TE83057-H-IQR
 Iteration No.: 00
 Attachment: 7.2 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 5 of 9

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification
Equipment #	TE83057	Equipment Name:	Detector Download Configuration System
Installation Site: Flex, 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 and Specification Procedure, 735001613, Version 25 Rev AB	Ready	<i>[Signature]</i> 24 AUG 2020
Comments: N/A <i>[Signature]</i> 24 AUG 2020			
Overall Test Conclusion ☐ Pass ☐ Fail		Document No.: <u>TE83057-4-IQR</u> Iteration No.: <u>00</u> Attachment: <u>7.3</u> Page: <u>1</u> of <u>1</u>	

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 7 of 9

Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE83507-4	Equipment Name:	PDA Detector Download Station	
Installation Site: Flex, 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
Part Number: 186018007 Serial Number:		All required CTQ Specification measurements result in a Pass	Pass	<i>Edrus</i> 24 AUG 2020
Comments: <i>N/A</i> <i>Edrus</i> 24 AUG 2020				
Overall Test Conclusion		Document No.: <u>TE83057-4-IQR</u> Iteration No.: <u>00</u> Attachment: <u>7.4</u> Page: <u>1</u> of <u>1</u>		
☒ Pass ☐ Fail				

Waters Corporation - Test Record

Part Number: <u>186018007</u>	Product: <u>eLambda Detector</u>
Operator: <u>1093653</u>	Start Time: <u>08/18/2020, 15:26:</u>
Serial Number: <u>H20PPD001A</u>	End Time: <u>08/18/2020, 15:32:</u>
Test System: <u>Download-Configure System</u>	Order: <u>NA</u>
Test Software: <u>1.4</u>	Location: <u>Flextronics, SG</u>

TMD: NA

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

Name	LSL	Measurement	USL	Unit	Outcome
Firmware Download		Complete			PASS
Serial Number Set		Complete			PASS
Leak Detector Test		Passed			PASS
Electrical Safety		Passed			PASS

Acquity Premier eLambda PDA Download-Config Overall Result - PASS

Signed: <u>W. 1093653</u>	Date: <u>18 Aug 2020</u>
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END OF DATA

Document No.: TF83057-4-IQR
Iteration No.: 00
Attachment: 7.5 Page 1 of 1