

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

PREPARED BY

Name	Role	Signature	Date
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The "Prepared By" signature denotes that this document accurately describes the qualification activities.

REVIEWED BY

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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.

REVISION HISTORY

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

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 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:

RevLev	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	TE83057-4 PDA Detector Download Station Validation Assessment Form
ECO9236204	Engineering Change Request to release the Acquity Premier eLambda PDA