

INSTALLATION QUALIFICATION REPORT For the PDA Final Test System (TE82882-9)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		01 Sep 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.

REVISION HISTORY

VERSION:		ORIGINATOR:		Change ID:	
00		Emma Pierce		N/A	
SUMMARY OF CHANGE: FIRST DOCUMENT FOR APPROVAL					
01		James J.Stors		N/A	
SUMMARY OF CHANGE: NEW SOFTWARE VERSION TO PRINT SERIAL NUMBER IN REPORT FOLDER					
02		Luo Huazhen		N/A	
SUMMARY OF CHANGE: NEW SOTFWARE VERSION TO ADD OPTICS BENCH PART NUMBERS					
03		Luo HuaZhen		9236204	
SUMMARY OF CHANGE: NEW ACQUITY PREMIER PART NUMBER ADDED					

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 TE82882-9, Final Test Station as defined in TE82882-07AUG2020-VAF and TSP 735001613, ACQUITY PDA Final Instrument Test and Specification Procedure, Version 25

SYSTEM BACKGROUND

The TE82882-9, PDA Final Test Station, is located at Flex Pte Ltd in Singapore and is used to perform functionality testing of Waters Corporation's Photo Diode Arrays (PDA's) as defined in TSP 735001613, to ensure compliance to the defined Manufacturing Test Specifications.

The system is comprised of a PC running a custom software program and uses serial and ethernet ports to communicate to up to four (4) UUT's in order to test Noise, Drift and Optics. Upon completion a Final Test Record is automatically generated, and a hard copy is printed. In addition, the Final Test Record is sent to the SigmaProd server.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82882-9, Final Test Station, based on the requirements of the executed protocol, 730004135, Installation Qualification Protocol, as detailed in Final Test Station and as defined in TE82882-07AUG2020-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82882-9, was tested in accordance with the applicable sections of 730004135, Installation Qualification Protocol, Version 03 per Final Test Station as defined in TE82882-07AUG2020-VA. 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 TE82882-9, remains compliant with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE82882-9, 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 who perform the TE82882-9 Final Test Station installation qualification was trained according 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 TE82882-9, was trained to 735001613, ACQUITY PDA Final Instrument Test and Specification Procedure Ver 25 and a Training Record is provided 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 03 and 735001613, ACQUITY PDA Final Instrument Test and Specification Procedure Ver 25, Final Test Station

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

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

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 TE82882-07AUG2020-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 TE82882-9 TE82882-07AUG2020-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 TE82882-9 TE82882-07AUG2020-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 TE82882-9 TE82882-07AUG2020-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 TE82882-9 TE82882-07AUG2020-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 and TE82882-07AUG2020-VAF.

6.6.1 IQ-06, Functional Verification Data Sheet is provided as attachment 7.4

6.6.2 One (1) UUT, part number 186018007, ACQUITY Premier eLambda PDA, H2OPPD001A was selected for the Functional Verification UUT as the change summarized in TE82882-07AUG2020-VAF, and met the requirement of obtaining a Final Test Record with the UUT serial number correctly listed and all results passed.

6.6.2.1 The Final Test Record showing the passing results 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: H2OPPD001A

8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution the 730004135, Installation Qualification Procedure, Version 03, for TE82882-9, Final Test Station per change outlined in TE82882-07AUG2020-VAF

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	ACQUITY PDA Final Instrument Test and Specification Procedure
TE82882-07AUG2020-VAF	TE82882-9 Acquity Final Test System Validation Assessment Form
ECO9236204	Engineering Change Request to release the Acquity Premier eLambda PDA

Title: individual Training Form

Document No: 730002657

Version No: 00

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Training Type:	Read and Understood		
Name:	Luo HuaZhen	Employee ID¹	618078
Date of Training	19SEP2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	03


Senior Test Engineer
19SEP2019
 Employee's Signature Title Date

N/A self trained
JG 19SEP2019
 Trainer's Signature Title Date

¹ Without preceding "90"

Installation Qualification Protocol

Document # 730004135

Version # 03

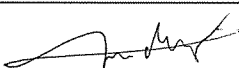
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Appendix A: TRAINING RECORD

Document #	735001613	Document Title	PDA Final Instrument TSP	Version	25
				Revision	N/A

☒ 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

N/A
JMD
17 Aug 2020

Print multiple copies of this Training Record Template as needed

Document No.: TE82882-9-IQR
Iteration No.: 03
Attachment: 7.2 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

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[illegible]

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE82882-9	Equipment Name:	PDA Final Test System	
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	HZ 01Sep2020
Comments: N/A HZ 01Sep2020				
Overall Test Conclusion			Document No.: TE82882-9-IQR Iteration No.: 03 Attachment: 7.4 Page: 1 of 1	
☒ Pass ☐ Fail				

Waters Corporation - Test Record

Part Number: <u>186018007</u>	Product: <u>Acquity Premier eLambda PDA</u>
Operator: <u>1093653</u>	Start Time: <u>08/18/2020, 16:06:</u>
Serial Number: <u>H20PPD001A</u>	End Time: <u>08/18/2020, 16:51:</u>
Test System: <u>TE82882-9</u>	Order: <u>NA</u>
Test Software: <u>4.2</u>	Location: <u>Flextronics, SG</u>

TMD: NA

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

Name	LSL	Measurement	USL	Unit	Outcome
Baseline Temperature (Audit)	20	25.55	40	Degrees C	PASS
Hot Baseline (Audit)	20	26.38	40	Degrees C	PASS
F1 alone (Audit)	20	27.66	40	Degrees C	PASS
F1 and F2 (Audit)	20	25.28	40	Degrees C	PASS
Electrical Safety		True			PASS
Lambda1	178	186.4293	188	nM	PASS
Lambda512	801.5	804.6227	811.5	nM	PASS
Shunt/Cell energy 5ms	80000	104531	250000	counts	PASS
Total Runs	0	2	24		PASS
Noise Runs	0	2	5		PASS
Final Noise	0	5.47	7	uAu	PASS
Final Drift	-1000	-659	1000	uAu	PASS

Acquity Premier eLambda PDA Final Test Overall Result

- PASS

Signed: <i>we</i> <i>1093653</i>	Date: <i>18 Aug 2020</i>
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END OF DATA