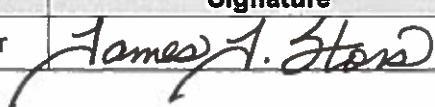


Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Installation Qualification Report	
Report No: TE82882-8-IQR	Iteration No: 01	SAP No: TE0082882QX	

INSTALLATION QUALIFICATION REPORT

For the 2998 Final Test System (TE82882-8)

PREPARED BY

Name	Role	Signature	Date
James J. Stors	Senior Test Validation Engineer		28 FEB 2018

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principal Test Engineer		28 FEB 2018

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		24 AUG 2018

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.
01	James J. Stors	New software version to print serial number in the Report footer.

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1.0 Purpose

The 2998 Final Test System, TE82882-8, is located in Singapore at contract manufacturer Flextronics. The 2998 Final Test System is used to perform functionality testing of Waters Corporation's 2998 Photo Diode Arrays (PDA's) as defined in TSP 735001613, to ensure compliance to the defined Manufacturing Test Specifications.

The system uses serial 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 of Report

This Test Equipment Report details the IQ activities undertaken for the 2998 Final Test System (TE82882-8) based on the requirements of the performed Installation Qualification, 730004135, Version 00 as outlined by the Test Software Version 4.1 risk assessment, per TE82882-09FEB18-VAF.

The risk assessment, based on this change, resulted in the requirement of performing the following test scripts:

- IQ-01 Associated Documentation Verification: To verify that the PDA Final Test System Test and Specification Procedure, 735001613, that references the new software version, 4.1, is in the appropriate state in SAP.
- IQ-04 Test Software Version: To verify the version specified within the PDA Final Test, Test and Specification Procedure, 735001613, matches the version of the program.
- IQ-06 Functional Verification: To verify that the entered UUT Serial Number is correctly listed at the bottom of the Test Record.

All other testing performed, as detailed in TE82882-8-IQR, Iteration 00, remains valid and applicable as there is no change to the installation site, calibration and PM schedule, or the safety and alarms.

3.0 Summary of Results - Statement of Fitness for Intended Use

The 2998 Final Test System (TE82882-8) was tested in accordance with the applicable sections of the Installation Qualification Protocol, 730004135, Version 00, as outlined in the Test Software Version 4.1 risk assessment, per TE82882-09FEB18-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 2998 Final Test System (TE82882-8) remains compliant with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the 2998 Final Test System (TE82882-8) remains fully qualified and fit for intended use post the change, as outlined in TE82882-09FEB18-VAF.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
UUT	Unit Under Test
PDA	Photo Diode Array
SAP	Enterprise Resource Planning (ERP) software
TSP	Test Specification and Procedure
PM	Preventive Maintenance
VAC	Volts Alternating Current
Hz	Hertz
°C	Degrees Celsius
N/A	Not Applicable

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5.0 Training

The Engineer who performed the 2998 Final Test System (TE82882-8) Installation Qualification is the Author of the Installation Qualification Procedure, 730004135, Version 00, and is therefore trained.

The Operator who performed the testing of the UUT using the 2998 Final Test System (TE82882-8) per Installation Qualification Procedure, 730004135, Version 00, IQ-06, Functional Verification test Script, has been trained to the updated PDA Final Test System Test and Specification Procedure, 735001613, Version 20. A copy of the Training Record is provided as Attachment 7.1.

6.0 Qualification Results

6.1 Test Script IQ-01, Associated Documentation Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 00, for the PDA Final Test System Test and Specification Procedure, 735001613, as outlined in TE82882-09FEB18-VAF.

6.1.1 IQ-01, Associated Documentation Verification Data Sheet, is provided as Attachment 7.2.

6.1.2 The updated PDA Final Test System Test and Specification Procedure, 735001613, Version 20, was confirmed to have been updated with software version 4.1 and to be in SAP with a status of Ready. A screen capture is provided below:

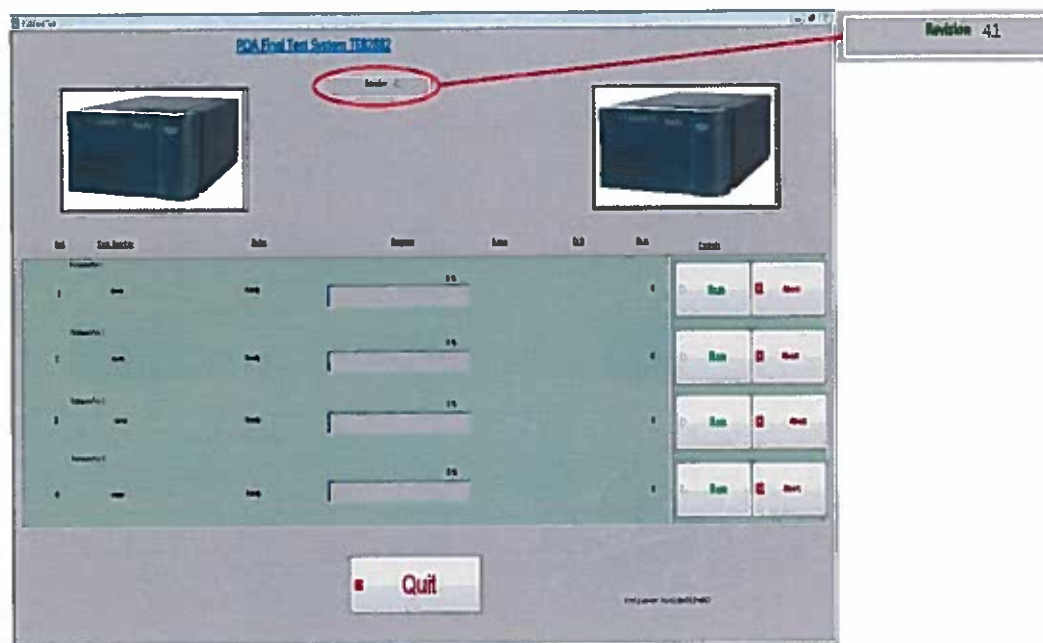
Document List After Selection 21 Hits											
											
Rev	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
	TSP	735001613	00	000	Acquity PDA Final Test	RELEASE GENERAL	8	06/25/2007	03/30/2008		Eric Tumer
	TSP	735001613	01	000	Acquity PDA Final Test	ABANDON					Bruce Porter
B	TSP	735001613	02	000	Acquity PDA Final Test	RELEASE GENERAL	8	03/31/2008	05/11/2008	9134035	Eric Tumer
C	TSP	735001613	03	000	Acquity PDA Final Test	RELEASE GENERAL	8	05/12/2008	07/09/2008	9134937	Eric Tumer
D	TSP	735001613	04	000	PDA Final test	RELEASE GENERAL	8	07/10/2008	12/03/2008	9136327	Eric Tumer
E	TSP	735001613	05	000	PDA Final test	RELEASE GENERAL	8	12/04/2008	03/29/2009	9139040	Eric Tumer
F	TSP	735001613	06	000	PDA Final test	RELEASE GENERAL	8	03/30/2009	05/21/2009	9140911	Eric Tumer
G	TSP	735001613	07	000	PDA Final test	RELEASE GENERAL	8	05/22/2009	07/01/2010	9142852	Eric Tumer
H	TSP	735001613	08	000	PDA Final test	RELEASE GENERAL	8	07/02/2010	11/22/2010	9153554	Eric Tumer
J	TSP	735001613	09	000	PDA Final test	RELEASE GENERAL	8	11/23/2010	07/04/2012	9157158	Chris Green
	TSP	735001613	10	000	PDA Final test	ABANDON					Eric Tumer
K	TSP	735001613	11	000	PDA Final test	RELEASE GENERAL	8	07/05/2012	02/09/2014	9171410	Eric Tumer
L	TSP	735001613	12	000	PDA Final test	RELEASE GENERAL	8	02/10/2014	02/18/2014	9185711	Chris Green
M	TSP	735001613	13	000	PDA Final test	RELEASE GENERAL	8	02/19/2014	10/12/2014	9186532	Eric Tumer
N	TSP	735001613	14	000	PDA Final test	RELEASE GENERAL	8	10/13/2014	03/24/2015	9192039	Eric Tumer
	TSP	735001613	15	000	PDA Final test	ABANDON					Eric Tumer
P	TSP	735001613	16	000	PDA Final test	RELEASE GENERAL	8	03/25/2015	07/12/2015	9195587	Eric Tumer
R	TSP	735001613	17	000	PDA Final test	RELEASE GENERAL	8	07/13/2015	12/10/2015	9198916	Eric Tumer
T	TSP	735001613	18	000	PDA Final test	RELEASE GENERAL	8	12/11/2015	11/28/2017	9202728	Tyler Modelski
U	TSP	735001613	19	000	PDA Final test	RELEASE GENERAL	8	11/29/2017	12/31/9999	9218596	Eric Tumer
	TSP	735001613	20	000	PDA Final test	READY					Eric Tumer

6.1.3 Post execution, but prior to approval, the TSP was modified for clerical reasons that did not change the test steps that were performed.

6.2 Test Script IQ-04, Test Software and Instrument Firmware Version, was performed in accordance with Installation Qualification Protocol, 730004135, Version 00, for the updated software version 4.1, as outlined in TE82882-09FEB18-VAF.

6.2.1 IQ-04, Test Software and Instrument Firmware Version Data Sheet, is provided as Attachment 7.3.

6.2.2 The Test Equipment Software version listed in 735001613, PDA Final Test System Test and Specification Procedure (Version 20), is 4.1 and was verified to match the revision (listed as Revision on the Operator Interface) displayed on the Test Equipment PDA Final Test System TE82882 program display, as shown in the screen capture below:



6.3 Test Script IQ-06, Functional Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 00, for the updated software version 4.1, as outlined in TE82882-09FEB18-VAF.

6.3.1 IQ-06, Functional Verification Data Sheet is provided as Attachment 7.4.

6.3.2 One (1) UUT, Part Number 186015032, was tested using the TE82882-8, 2998 Final Test System, and met the requirement of obtaining a Final Test Record with the UUT Serial Number correctly listed at the bottom of the Test Record.

6.3.2.1 The Instrument Final Test Record is provided as Attachment 7.5.

6.4 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 7.2	None
IQ-04	Pass	Attachment 7.3	None
IQ-06	Pass	Attachment 7.4 and 7.5	None

7.0 Attachments

7.1 Training Record to 735001613 – PDA Final Test System – Joel Mamalateo Deduyo

7.2 IQ-01, Associated Documentation Verification Test Script Data Sheet

7.3 IQ-04, Test Software and Instrument Firmware Version Test Script Data Sheet

7.4 IQ-06, Functional Verification Test Script Data Sheet

7.5 Instrument Final Test Record for IQ-06, Part Number: 186015032, Serial Number: B18UPD140A

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8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the Installation Qualification, 730004135, Version 00, for the 2998 Final Test System (TE82882-8), as outlined in the Test Software Version 4.1 risk assessment, per TE82882-09FEB18-VAF.

9.0 References

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

Document Number	Document title
730004135, Version 00	Installation Qualification Protocol
TE82882-09FEB18-VAF	Test Software Version 4.1 risk assessment
735001613 Version 20	PDA Final Test System Test and Specification Procedure

Appendix A: TRAINING RECORD

Document No. 735001613 Procedure Title PDA Final Test System Test and Specification Procedure Version 20

Training by: N/A 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.

[illegible]

Copy this Training Record Template as needed

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

Document No.: TE82882-8-1QR
Iteration No.: 01
Attachment: 7.1 Page: 1 of 1

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test name: Associated Documentation Verification		Test Script No.: IQ-01	
Equipment No./ID: TE82882-8		Equipment Name: PDA Final Test System	
Installation Site: Contract Manufacturer 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 - Test and Specification Procedure; 735001613; Version 20	READY	AS 28 FEB 2018
Comments: N/A James A. Stead 28 FEB 2018			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IOQ Test name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04	
Equipment No./ID: TE82882-8		Equipment Name: PDA Final Test System		
Installation Site: Contract Manufacturer 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: 4.1	Version: 4.1	PASS	AS 28 FEB 2018
Comments: <i>N/A</i> <i>James A. Stern</i> <i>28 FEB 2018</i>				
Overall Test Conclusion: ☒ Pass ☐ Fail				

Copy this Test Script as needed

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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Copy this Test Script as needed

IOQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE82882-8		Equipment Name: PDA Final Test System	
Installation Site: Contract Manufacturer 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: 186015032 UUT Serial Number: B18UPD140A	The UUT Serial Number is correctly listed at the bottom of the Test Record.	PASS	 28 FEB 2018
Comments:  28 FEB 2018			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Waters Corporation - Test Record

Part Number: 186015032

Product: Acquity PDA

Operator: 246154

Start Time: 02/22/2018, 13:49:

Serial Number: B18UPD140A

End Time: 02/22/2018, 17:55:

Test System: TE82882-8

Order: NA

Test Software: 4.1

Location: Flextronics,SG

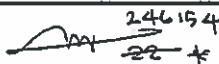
TMD: NA

Firmware: 1.69 Build#: 6347 (Aug 16 2017)

Name	LSL	Measurement	USL	Unit	Outcome
Baseline Temperature (Audit)	20	22.58	40	Degrees C	PASS
Hot Baseline (Audit)	20	22.66	40	Degrees C	PASS
F1 alone (Audit)	20	23.15	40	Degrees C	PASS
F1 and F2 (Audit)	20	23.62	40	Degrees C	PASS
Electrical Safety		True			PASS
Lambda1	178.375	186.884	188.375	nM	PASS
Lambda512	501.25	502.2498	511.25	nM	PASS
Shunt/Cell energy 5ms	80000	192000	250000	counts	PASS
Total Runs	0	13	24		PASS
Noise Runs	0	1	5		PASS
Final Noise	0	3.39	7	uAu	PASS
Final Drift	-1000	991	1000	uAu	PASS

PDA Final Test Overall Result - PASS

Signed:

 246154

Date:

22 FEB 2018

END OF DATA

+ correction of wrong entry

246154  22 FEB 2018