

 THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE82969-1-IQR	Iteration No: 01	SAP No: TE0082969QX	

INSTALLATION QUALIFICATION REPORT

For the PDA / eLambda Linearity Tester (TE82969-1)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		

REVIEWED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		
Eric Turner	Principal Test Engineer		

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		

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	Luo HuaZhen	Firmware Update

 THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report	
Report No: TE82969-1-IQR	Iteration No: 01	SAP No: TE0082969QX

1.0 Purpose

The PDA / eLambda Linearity Tester (TE82969-1) is located in the Flextronics Contractor Manufacturer site in Singapore. This station is used to verify that linearity of PDA Detectors of the following part numbers is within specification: 186015034, 186015053, 279002224, 279002897, 800000414 and 800000439. The manual firmware download for these part numbers is most commonly done at the TE82969 system although it is unrelated to the Linearity and Wavelength Accuracy tests that are the primary purpose of the PDA/eLambda Linearity Test System. After the instrument firmware download is complete, the UUT undergoes wavelength calibration using custom software at the TE82969 system, then it is moved to the 2998 Final Test System (TE82882) to test noise, drift, and optics.

This Installation Qualification is being performed as required by the Validation Assessment Form TE82969-06JUL2018-VAF which can be found in the TE0082969QX directory of SAP.

2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the PDA / eLambda Linearity Tester (TE82969-1) based on the requirements of the Installation Qualification Procedure 730004135, Ver. 00 and TE82969-06JUL2018-VAF.

This Installation Qualification Report defines the documents used to qualify the PDA / eLambda Linearity Tester (TE82969-1).

3.0 Summary of Results - Statement of Fitness for Intended Use

The PDA / eLambda Linearity Tester was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 00 and TE82969-06JUL2018-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 PDA / eLambda Linearity Tester complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the PDA / eLambda Linearity Tester (TE82969-1) can be considered fully qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
BOM	Bill of Materials
CAL/PM	Calibration/Preventive Maintenance
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
N/A	Not Applicable
P/N	Part Number
PC	Personal Computer
PDA	Photo Diode Array
SAP	Enterprise Resource Planning Software
S/N	Serial Number
TSP	Test Specification and Procedure
UUT	Unit Under Test
VAF	Validation Assessment Form

 THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE82969-1-IQR	Iteration No: 01	SAP No: TE0082969QX	

5.0 Training

The operator of the PDA / eLambda Linearity Tester (TE82969-1) was trained according to the UPC2 PDA and Veyron PDA Final Test Procedure 735002531, Ver. 09. The executors of this qualification were trained according to the Installation Qualification Procedure 730004135, Ver. 00. Both training records are provided as Attachment 7.1 and 7.2, respectively.

6.0 Qualification Results

- 6.1 Test Script IQ-01: Associated Documentation Verification, Test Script IQ-02: Site Verification, and Test Script IQ-03: Instrumentation Calibration Verification were not performed according to Validation.
- 6.2 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.3.
 - 6.2.1 The TE82969 Test Equipment Software version listed in UPC2 PDA and Veyron PDA Final Test Procedure 735002531, Ver. 09 is Test Software 2.0 and was verified to match the version listed on the Test Record. The Test Record is provided as Attachment 7.4 and 7.5.
 - 6.2.2 The firmware version listed in ECR #9222852 for part numbers 186015034 and 186015053 is 1.70.6367 and was verified to match the version listed on the Test Record. The test records are provided as Attachments 7.4 and 7.5.
- 6.3 Test Script IQ-05: General Safety and Alarms was not performed according to TE82969-06JUL2018-VAF.
- 6.4 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.6.
 - 6.4.1 One (1) UUT (P/N: 186015034, S/N: G18C2P393A) was tested using the PDA / eLambda Linearity Tester (TE82969-1) with all tests passing. Refer to Attachment 7.7 for the passing Test Record.
 - 6.4.2 One (1) UUT (P/N: 186015053, S/N: G18ADT145A) was tested using the PDA / eLambda Linearity Tester (TE82969-1) with all tests passing. Refer to Attachment 7.8 for the passing Test Record.
- 6.5 This table provides a summary of each test script as performed according to 730004135, Ver. 00 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-04	Pass	Attachments 7.4, and 7.5	None
IQ-06	Pass	Attachments 7.7 and 7.8	None

7.0 Attachments

- 7.1 Completed Operator Training Record 735002531, Ver. 09
- 7.2 Completed Executor Training Record 730004135, Ver. 00
- 7.3 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.4 Objective Evidence IQ-04: Passing Test Record for UUT Part #186015034 (G18C2P393A)
- 7.5 Objective Evidence IQ-04: Passing Test Record for UUT Part #186015053 (G18ADT145A)
- 7.6 Completed Test Script IQ-06: Functional Verification
- 7.7 Objective Evidence IQ-06: Passing Final Test Record for UUT Part #186015034 (G18C2P393A)
- 7.8 Objective Evidence IQ-06: Passing Final Test Record for UUT Part #186015053 (G18ADT145A)

 THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE82969-1-IQR	Iteration No: 01	SAP No: TE0082969QX	

8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the Installation Qualification Procedure 730004135, Ver. 00.

9.0 References

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

Document Number	Document Title
730004135, Ver. 00	Installation Qualification Procedure
735002531, Ver. 09	UPC2 PDA and Veyron PDA Final Test Procedure
735003437, Ver. 00	PDA Linearity Test System PM Procedure
721007611, Ver. 01	2998 PDA Detector Functional Specification
TE0082969QX	Validation Assessment Form TE82969-06JUL2018-VAF