

 THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE83057-4-IQR	Iteration No: 02	SAP No: TE0083057QX	

INSTALLATION QUALIFICATION REPORT

For the PDA Detector Download Station (TE83057-4)

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	Emma Pierce	Firmware update
02	Luo HuaZhen	Firmware update

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1.0 Purpose

The PDA Detector Download Station (TE83057-4) is located in the Flextronics Contract Manufacturer Site in Singapore. This station is used to download instrument firmware to the following part numbers: 186015026, 186002998, 186015032, 186015033, 186015030, 700002787, 700004035, 700005424, 700005427, 186299800, N2971013, N2971035, 186020003, 186017003, 279002655, and 186017013. After the instrument firmware download is complete, the UUT is moved to the PDA / eLambda Linearity Test System (TE82969) to undergo wavelength calibration, then to the 2998 Final Test System (TE82882) to test noise, drift, and optics

The PDA Detector Download Station is equipped with a computer and the appropriate cables to connect the UUT to the computer. Once the UUT is connected, the operator selects the appropriate part number from the test software and begins the download. When the download is complete a test record is automatically generated and a hard copy is printed for the operator to collect.

This Installation Qualification is being performed as required by the Validation Assessment Form TE83057-06JUL2018-VAF which can be found in the TE0083057QX directory of SAP.

2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the PDA Detector Download Station (TE83057-4) based on the requirements of the Installation Qualification Procedure 730004135, Ver. 00 and TE83057-06JUL2018-VAF.

This Installation Qualification Report defines the documents used to qualify the PDA Detector Download Station (TE83057-4).

3.0 Summary of Results - Statement of Fitness for Intended Use

The PDA Detector Download Station was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 00 and TE83057-06JUL2018-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 Detector Download Station complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the PDA Detector Download Station (TE83057-4) can be considered qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
ECR	Engineering Change Request
IQ	Installation Qualification
IQR	Installation Qualification Report
N/A	Not Applicable
P/N	Part Number
PDA	Photo Diode Array
S/N	Serial Number
SAP	Enterprise Resource Planning Software
UPLC	Ultra Performance Liquid Chromatography
UUT	Unit Under Test

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Term	Explanation
VAF	Validation Assessment Form
WPPL	Waters Pacific Private Limited

5.0 Training

The operator of the PDA Detector Download Station (TE83057-4) was trained according to the PDA Final Test Procedure 735001613, Ver. 19. The executor of this qualification was trained according to the Installation Qualification Procedure 730004135, Ver. 00. Both training records are provided as Attachments 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 TE83057-06JUL2018-VAF.

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 TE83057 Test Equipment Software version listed in PDA Final Test Procedure 735001613, Ver. 19 is Test Software 1.4 and was verified to match the version listed on the test records. The test records are provided as Attachments 7.5, 7.6, 7.7, 7.8, 7.9 and 7.10.

6.2.2 The firmware version listed in ECR #9222852 for part numbers 186015032 and 186015033, is version 1.70.6367 and was verified to match the version listed on the test records. The test records are provided as Attachments 7.5 and 7.6.

6.2.3 The firmware version listed in ECR #9222852 for part numbers 186017003, 186017013, 186002998 and 186299800, is version 1.70.6363 and was verified to match the version listed on the test records. The test records are provided as Attachments 7.7, 7.8, 7.9 and 7.10.

6.3 Test Script IQ-05: General Safety and Alarms was not performed according to TE83057-06JUL2018-VAF.

6.4 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00 and TE83057-06JUL2018-VAF. The completed Test Script Data Sheets are provided as Attachments 7.4.

6.4.1 One (1) UUT (P/N: 186015032, S/N: G18UPD512A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.5.

6.4.2 One (1) UUT (P/N: 186015033, S/N: G18UPL056A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.6.

6.4.3 One (1) UUT (P/N: 186017003, S/N: G18VPD394A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.7.

6.4.4 One (1) UUT (P/N: 186017013, S/N: G18BPD043A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.8.

6.4.5 One (1) UUT (P/N: 186002998, S/N: G18998785A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.9.

6.4.6 One (1) UUT (P/N: 186299800, S/N: G18998771A) was tested using the PDA Detector Download Station (TE83057-4) with all tests passing. The passing test record is provided as Attachment 7.10.

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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 7.3, 7.5,7.6, 7.7,7.8, 7.9 and 7.10	None
IQ-06	Pass	Attachments 7.4, 7.5,7.6, 7.7,7.8, 7.9 and 7.10	None

7.0 Attachments

- 7.1 Completed Operator Training Record 735001613, Ver. 19
- 7.2 Completed Executor Training Record 730004135, Ver. 00
- 7.3 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.4 Completed Test Script IQ-06: Functional Verification
- 7.5 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186015032 (S/N: G18UPD512A)
- 7.6 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186015033 (S/N: G18UPL056A)
- 7.7 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186017003 (S/N: G18VPD394A)
- 7.8 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186017013 (S/N: G18BPD043A)
- 7.9 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186002998 (S/N: G18998785A)
- 7.10 Objective Evidence IQ-04 and IQ-06: Passing Test Record for UUT Part # 186299800 (S/N: G18998771A)

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
735001613, Ver. 19	PDA Final Test Procedure
721007611, Ver. 01	2998 PDA Detector Functional Specification
TE0083057QX	Validation Assessment Form TE83057-06JUL2018-VAF
ECR #9222852	Engineering Change Request to Release Firmware Update