



| Test Script #                                                                   | IQ-01     | IQ Test Name:   | Associated Documentation Verification |
|---------------------------------------------------------------------------------|-----------|-----------------|---------------------------------------|
| Equipment #                                                                     | TE82969-1 | Equipment Name: | PDA/Lambda Linearity Tester           |
| Installation Site: Flextronics Contract Manufacturing Site of WPPL in 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, then complete the table below. Rows may be added/removed as needed.
- All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section.

**Objective Evidence:**

- Completed IQ-01 Test Script Data Sheet
- SAP screenshots of below available document(s)

| Document Type | Title, Doc. #, Version/Revision #                                        | Status in SAP      | Initial & Date       |
|---------------|--------------------------------------------------------------------------|--------------------|----------------------|
| TSP           | PDA Final Test - Test and Specification Procedure; 735001613; Version 20 | RELEASE<br>GENERAL | J M D<br>25 SEP 2018 |

**Comments:**

N/A

25 SEP 2018

|                                          |                               |                                      |
|------------------------------------------|-------------------------------|--------------------------------------|
| <b>Overall Test Conclusion</b>           |                               | Document No.: _____                  |
| <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail | Iteration No.: _____                 |
|                                          |                               | Attachment: _____ Page: ____ of ____ |

|                           |                                                               |                        |                                               |
|---------------------------|---------------------------------------------------------------|------------------------|-----------------------------------------------|
| <b>Test Script #</b>      | IQ-04                                                         | <b>IQ Test Name:</b>   | Test Software and Instrument Firmware Version |
| <b>Equipment #</b>        | TE82969-1                                                     | <b>Equipment Name:</b> | PDA/Lambda Linearity Tester                   |
| <b>Installation Site:</b> | Electronics Contract Manufacturing Site of WPPPL in Singapore |                        |                                               |

**Purpose:**

To verify that the installed software/firmware is correct per the applicable design and/or operational document(s).

**Test Execution:**

- List all relevant Equipment software and/or Instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed.
- List the associated required equipment software and/or critical instrument/Internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column.
- Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below.

**Objective Evidence:**

- Completed IQ-04 Test Script Data Sheet
- Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report.
- Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable

| Description             | Acceptance Criteria | As Found     | Pass/Fail | Initial & Date     |
|-------------------------|---------------------|--------------|-----------|--------------------|
| Test Equipment Software | Version: 2.1        | Version: 2.1 | PASS      | JMO<br>25 SEP 2018 |

**Comments:**

N/A

*[Signature]* 25 SEP 2018

|                                          |                               |                                                                                     |
|------------------------------------------|-------------------------------|-------------------------------------------------------------------------------------|
| <b>Overall Test Conclusion</b>           |                               | Document No.: _____<br>Iteration No.: _____<br>Attachment: _____ Page: ____ of ____ |
| <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |                                                                                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                           |                                                                                     |                            |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------|--|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | IQ-06                                                                     | <b>IQ Test Name:</b>                                                                | Functional Verification    |  |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | TE82969-1                                                                 | <b>Equipment Name:</b>                                                              | PDAlambda Linearity Tester |  |
| <b>Installation Site:</b> Flextronics Contract Manufacturing Site of WPPL in Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                           |                                                                                     |                            |  |
| <b>Purpose:</b><br>To verify that the system operates as expected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                           |                                                                                     |                            |  |
| <b>Test Execution:</b> <ul style="list-style-type: none"> <li>Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835.</li> <li>List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column.</li> <li>Define the appropriate Acceptance Criteria within the Acceptance Criteria column.</li> <li>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.</li> </ul>                                                                                                           |                                                                           |                                                                                     |                            |  |
| <b>Objective Evidence:</b> <ul style="list-style-type: none"> <li>Completed IQ-06 Test Script Data Sheet</li> <li>Copy of the Test Record(s) for the UUT(s), as applicable</li> <li>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.</li> <li>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.</li> <li>For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.</li> </ul> |                                                                           |                                                                                     |                            |  |
| <b>UUT Part Number/Serial Number</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Acceptance Criteria</b>                                                | <b>Pass/Fail</b>                                                                    | <b>Initial &amp; Date</b>  |  |
| UUT Part Number: 186015033                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 30mg concentration test runs and is properly reported on the Test Record. | PASS                                                                                | JMD<br>25 SEP 2018         |  |
| UUT Serial Number:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                           |                                                                                     |                            |  |
| <b>Comments:</b><br><div style="text-align: center;"> <p>N/A</p> <p><i>[Signature]</i></p> <p>25 SEP 2018</p> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                           |                                                                                     |                            |  |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                           | Document No.: _____<br>Iteration No.: _____<br>Attachment: _____ Page: ____ of ____ |                            |  |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                           |                                                                                     |                            |  |

# Waters Corporation - Test Record

Part Number: 186015033  
Operator: 842185  
Serial Number: J18UPL246A  
Test System: TE82969-1  
Test Software: 2.1

Product: eLambda PDA  
Start Time: 09/25/2018, 17:30:  
End Time: 09/25/2018, 17:32:  
Order: NA  
Location: Flextronics.SG

TMD: NA

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

| Name     | LSL | Measurement | USL | Unit | Outcome |
|----------|-----|-------------|-----|------|---------|
| %RSD     | 0   | 4.263       | 5   |      | PASS    |
| Mean     |     | 0.09        |     |      | PASS    |
| Std Dev  |     | 0.004       |     |      | PASS    |
| Lambda   |     | 257.6       |     |      | PASS    |
| A/C 5mg  |     | 0.0929      |     |      | PASS    |
| A/C 10mg |     | 0.0932      |     |      | PASS    |
| A/C 15mg |     | 0.0933      |     |      | PASS    |
| A/C 20mg |     | 0.0906      |     |      | PASS    |
| A/C 25mg |     | 0.0875      |     |      | PASS    |
| A/C 30mg |     | 0.0838      |     |      | PASS    |

**eLambda PDA Linearity Test Overall Result - PASS**

Signed: 

Date: 25 Sep 2018

END OF DATA