

## INSTALLATION QUALIFICATION REPORT For the PDA Final Test System (TE82882-13)

### PREPARED BY

| Name        | Role                 | Signature                                                                           | Date        |
|-------------|----------------------|-------------------------------------------------------------------------------------|-------------|
| Luo HuaZhen | Senior Test Engineer |  | 04 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 | SEE ATTACHED E-MAIL |      |

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

## HuaZhen Luo

---

**From:** Eric Turner  
**Sent:** Friday, 4 September, 2020 20:10  
**To:** HuaZhen Luo  
**Subject:** RE: IQRs for approval \_PDA

This email serves as my digital signature according to TMD010801

Best Regards,

**Eric Turner**  
Principal Test Engineer

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Waters Corporation  
34 Maple Street  
Milford  
MA 01757  
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---

**From:** HuaZhen Luo <HuaZhen\_Luo@waters.com>  
**Sent:** Friday, September 4, 2020 3:04 AM  
**To:** Eric Turner <Eric\_Turner@waters.com>  
**Subject:** RE: IQRs for approval \_PDA

Hi Eric,

The attached is last 2x PDA final test station TE82882-13 and TE82882-14 IQR for Premier product.  
Please review and sign off this IQR.

**Luo HuaZhen**  
Senior Test Engineer

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---

**From:** Eric Turner <[Eric\\_Turner@waters.com](mailto:Eric_Turner@waters.com)>  
**Sent:** Tuesday, 1 September, 2020 20:42  
**To:** HuaZhen Luo <[HuaZhen\\_Luo@waters.com](mailto:HuaZhen_Luo@waters.com)>  
**Subject:** RE: IQRs for approval \_PDA

Hello,

This email serves as my digital signature according to TMD010801

Best Regards,

**Eric Turner**  
Principal Test Engineer

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USA

---

**From:** HuaZhen Luo <[HuaZhen\\_Luo@waters.com](mailto:HuaZhen_Luo@waters.com)>  
**Sent:** Tuesday, September 1, 2020 3:04 AM

**To:** Eric Turner <[Eric\\_Turner@waters.com](mailto:Eric_Turner@waters.com)>

**Subject:** IQRs for approval \_PDA

Hi Eric,

Please kindly review and approve the attached IQR for Acquity Premier PDA final test stations TE82882-9, -10 and -11 in Flex.

Thank you

**Luo HuaZhen**  
Senior Test Engineer

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## 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 TE82882-13, 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 TE82882-13, 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 TE82882-13, 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 TE82882-13, 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 TE82882-13, remains compliant with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE82882-13, 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 TE82882-13 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 TE82882-13, 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:

| RevLev | 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 TE82882-13 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 TE82882-13 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 TE82882-13 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 TE82882-13 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, H2OPPD016A 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: H2OPPD016A

## 8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution the 730004135, Installation Qualification Procedure, Version 03, for TE82882-13, 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 | TE82882-13 Acquity Final Test System Validation Assessment Form       |
| ECO9236204            | Engineering Change Request to release the Acquity Premier eLambda PDA |



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FORM

Title: individual Training Form

Document No: 730002657

Version No: 00

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|                  |                     |                          |        |
|------------------|---------------------|--------------------------|--------|
| Training Type:   | Read and Understood |                          |        |
| Name:            | Luo HuaZhen         | Employee ID <sup>1</sup> | 618078 |
| Date of Training | 19SEP2019           |                          |        |
| Comments:        | N/A                 |                          |        |

| Document Number             | Title                               | Rev. # |
|-----------------------------|-------------------------------------|--------|
| 730004135                   | Installation Qualification Protocol | 03     |
| <del>N/A JG 19SEP2019</del> |                                     |        |
|                             |                                     |        |
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|                             |                                     |        |
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|                             |                                     |        |
|                             |                                     |        |
|                             |                                     |        |

JG Senior Test Engineer 19SEP2019  
Employee's Signature Title Date

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

<sup>1</sup> Without preceding "90"

## Installation Qualification Protocol

Document # 730004135

Version # 03

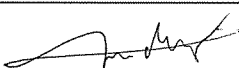
Page 8 of 9

### 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 |
|                       |                                                                                    |          |             |
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|                       |                                                                                    |          |             |

N/A  
JMD  
17 Aug 2020

Print multiple copies of this Training Record Template as needed

Document No.: TE82882-13-IQR  
 Iteration No.: 03  
 Attachment: 7.2 Page: 1 of 1

# Installation Qualification Protocol

Document # 730004135

Version # 03

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                               |                        |                                                                                                                              |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | IQ-01                                                                         | <b>IQ Test Name:</b>   | Associated Documentation Verification                                                                                        |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | TE82882-13                                                                    | <b>Equipment Name:</b> | PDA Final Test System                                                                                                        |                           |
| <b>Installation Site:</b> Flex, Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                               |                        |                                                                                                                              |                           |
| <p><b>Purpose:</b><br/>To verify that supporting documentation is available prior to the completion of qualification.</p> <p><b>Test Execution:</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul> <p><b>Objective Evidence:</b></p> <ul style="list-style-type: none"> <li>Completed IQ-01 Test Script Data Sheet</li> <li>SAP screenshots of below available document(s)</li> </ul> |                                                                               |                        |                                                                                                                              |                           |
| <b>Document Type</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Title, Doc. #, Version/Revision #</b>                                      |                        | <b>Status in SAP</b>                                                                                                         | <b>Initial &amp; Date</b> |
| TSP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | PDA Final Test System Test and Specification Procedure, 735001613, Version 25 |                        | Ready                                                                                                                        | HZ 04Sep2020              |
| <p><b>Comments:</b></p> <div style="text-align: center; height: 300px;">  <p>N/A HZ 04Sep2020</p> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                               |                        |                                                                                                                              |                           |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                               |                        | <p><b>Document No.:</b> TE82882-13-IQR</p> <p><b>Iteration No.:</b> 03</p> <p><b>Attachment:</b> 7.3 <b>Page:</b> 1 of 1</p> |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                               |                        |                                                                                                                              |                           |

## Installation Qualification Protocol

Document # 730004135

Version # 03

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |            |                                                              |                                                                                                               |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>Test Script #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | IQ-06      | <b>IQ Test Name:</b>                                         | Functional Verification                                                                                       |                           |
| <b>Equipment #</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | TE82882-13 | <b>Equipment Name:</b>                                       | PDA Final Test System                                                                                         |                           |
| <b>Installation Site:</b> Flex, Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |            |                                                              |                                                                                                               |                           |
| <p><b>Purpose:</b><br/>To verify that the system operates as expected.</p> <p><b>Test Execution:</b></p> <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> <p><b>Objective Evidence:</b></p> <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> |
| Part Number: 186018007<br>Serial Number: H20PPD016A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |            | All required CTQ Specification measurements result in a Pass | Pass                                                                                                          | HZ 04Sep2020              |
| <p><b>Comments:</b></p> <div style="text-align: center; height: 150px;"> <p>N/A HZ 04Sep2020</p> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |            |                                                              |                                                                                                               |                           |
| <b>Overall Test Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |                                                              | <b>Document No.:</b> TE82882-13-IQR<br><b>Iteration No.:</b> 03<br><b>Attachment:</b> 7.4 <b>Page:</b> 1 of 1 |                           |
| <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |            |                                                              |                                                                                                               |                           |

# Waters Corporation - Test Record

|                                  |                                             |
|----------------------------------|---------------------------------------------|
| Part Number: <u>186018007</u>    | Product: <u>Acquity Premier eLambda PDA</u> |
| Operator: <u>246154</u>          | Start Time: <u>08/28/2020, 10:06:</u>       |
| Serial Number: <u>H20PPD016A</u> | End Time: <u>08/28/2020, 11:11:</u>         |
| Test System: <u>TE82882-13</u>   | Order: <u>N/A</u>                           |
| Test Software: <u>4.2</u>        | Location: <u>Flextronics, SG</u>            |

TMD: N/A

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

| Name                         | LSL   | Measurement | USL    | Unit      | Outcome |
|------------------------------|-------|-------------|--------|-----------|---------|
| Baseline Temperature (Audit) | 20    | 22.3        | 40     | Degrees C | PASS    |
| Hot Baseline (Audit)         | 20    | 22.59       | 40     | Degrees C | PASS    |
| F1 alone (Audit)             | 20    | 23.46       | 40     | Degrees C | PASS    |
| F1 and F2 (Audit)            | 20    | 22.63       | 40     | Degrees C | PASS    |
| Electrical Safety            |       | True        |        |           | PASS    |
| Lambda1                      | 178   | 186.2925    | 188    | nM        | PASS    |
| Lambda512                    | 801.5 | 804.5917    | 811.5  | nM        | PASS    |
| Shunt/Cell energy 5ms        | 80000 | 112626      | 250000 | counts    | PASS    |
| Total Runs                   | 0     | 3           | 24     |           | PASS    |
| Noise Runs                   | 0     | 1           | 5      |           | PASS    |
| Final Noise                  | 0     | 5.56        | 7      | uAu       | PASS    |
| Final Drift                  | -1000 | 57          | 1000   | uAu       | PASS    |

**Acquity Premier eLambda PDA Final Test Overall Result  
- PASS**

|                           |                          |
|---------------------------|--------------------------|
| Signed: <u>Li 1093658</u> | Date: <u>28 Aug 2020</u> |
|---------------------------|--------------------------|

END OF DATA

Document No.: TE82882-13-IQR

Iteration No.: 03

Attachment: 7.5 Page: 1 of 1