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| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.™</small> | Validation Assessment Form |
| Document #: TE82882-10SEP19-VAF                                  | SAP #: TE0082882QX         |

**VALIDATION ASSESSMENT**  
For the TE82882 – PDA Detector Final Station

**PREPARED BY**

| Name        | Role                 | Signature                                                                          | Date        |
|-------------|----------------------|------------------------------------------------------------------------------------|-------------|
| Luo HuaZhen | Senior Test Engineer |  | 12 Sep 2019 |

**REVIEWED BY**

| Name         | Role                    | Signature | Date |
|--------------|-------------------------|-----------|------|
| Eric Turner  | Principle Test Engineer |           |      |
| Chan Yee Hwa | Manufacturing Engineer  |           |      |

**APPROVED BY**

| Name         | Role                             | Signature | Date |
|--------------|----------------------------------|-----------|------|
| Tan Kah Chin | Senior Quality Assurance Manager |           |      |

The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

The "Reviewed By" signature[s] denotes agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the TE82882 PDA Detector Final Test Stations.

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## 1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the released PDA Detector Final Test Stations (TE82882). This document shall also define the deliverable(s) required to maintain the equipment qualification, based on the engineering change. Qualification of the equipment shall ensure that it functions within its specifications.

## 2. BACKGROUND

The ACQUITY Arc Bio 2998 PDA Detector Final Test Station, TE82882, is used to verify functionality of the Photo Diode Array (PDA) Detector via controlled noise and drift tests.

The TE82882 automated test station is capable of testing the following Waters LC Part Numbers per the associated TSP:

TSP 735001613: 186002998, 186015026, 186015030, 186015032, 186015033, 186015034, 186015053, 186017003, 186017013, 186299800, 279002655, 700002787, 700003765, 700004035, 700005424, 700005427, 700009014, 700009328, 700009532, 700011650, 700011652, 700011867, 700011868, 700011869, 700012243, 700012245, 800000202, 800000244, 800000245, 800000304, 800000305, 800000397, 800000414, 800000439, 800000453, 800000476, N2971013 and N2971035

## 3. DESCRIPTION OF CHANGE

3.1. UPDOB2 and 3 are arbitrary labels used in the PDAIni.txt file. The spare part number cannot be tested due to wrong arbitrary labels used in PDAIni.txt file. In order to run spare part number 700011652 testing on PDA Detector Final Test Station, changed this arbitrary label from UPDOB2 to UPDOB3 by editing PDAIni.txt file. UPDOB3 is a fine label if it is a PDA optics bench (UPD = PDA OB = optics bench). The source code need not change.

## 4. RISK ASSESSMENT

### 4.1. High Risk Assessment

Please check the appropriate boxes below to determine the high risk assessed qualification or requalification requirements:

| 4.1.1. Specification                                                                                                                                                              | No                                  | Yes                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a test specification value being modified and/or added?                                                                                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 4.1.2. Software/Firmware                                                                                                                                                          | No                                  | Yes                      |
| Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result?                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is the change due to firmware downloaded to the UUT by a test system?                                                                                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is the change a flash file update?                                                                                                                                                | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is it a change to an existing, or the addition of a new, PCB Test Sequence?                                                                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)                                                                                                              | No                                  | Yes                      |
| Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 4.1.4. Equipment/Process Moves                                                                                                                                                    | No                                  | Yes                      |
| Is the change a move of the equipment, test method or process, to a different facility?                                                                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

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#### 4.2. Medium Risk Assessment

Please check the appropriate boxes below to determine the medium risk assessed qualification or requalification requirements:

|                                                                                            |                                     |                                     |
|--------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|
| <b>4.2.1. Replacement of Non-Identical</b>                                                 | <b>No</b>                           | <b>Yes</b>                          |
| Is the change due to a replacement of a system component with a non-identical equivalent?  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| <b>4.2.2. Computer Related or Replacement of Custom PCBs</b>                               | <b>No</b>                           | <b>Yes</b>                          |
| Is the change an update to the PC operating system?                                        | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Is the change a computer or printed circuit board replacement?                             | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| <b>4.2.3. Software/Firmware</b>                                                            | <b>No</b>                           | <b>Yes</b>                          |
| Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?    | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| Is the change a test system instrument firmware update (i.e. update to a stack component)? | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| <b>4.2.4. Equipment/Process Moves</b>                                                      | <b>No</b>                           | <b>Yes</b>                          |
| Is the change a move of the equipment, test method or process, within the Milford site?    | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |

4.3. This change results in a Medium Risk Assessment and the associated requalification requirements, as detailed in Section 6.0.

#### 5. HAZARD ASSESSMENT:

No known hazard impact to the environment, operator, assembler, service technician and end user due to the change.

#### 6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

|                                                                                                                                                                                                                                 |                                     |                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| <b>6.1. Equipment Design Verification (EDV)</b>                                                                                                                                                                                 | <b>No</b>                           | <b>Yes</b>               |
| Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?                                                                                                                            | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)                                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br>This correction is only to edit the PDAInit.txt file that can be detected by the system using the existing software. The change does not affect the software, design or control of the system. |                                     |                          |
| <b>6.2. Installation Qualification (IQ)</b>                                                                                                                                                                                     | <b>No</b>                           | <b>Yes</b>               |
| Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br>This correction does not affect software, design or control of the system so no IQ is recommended.                                                                                             |                                     |                          |

|                                                   |                                   |
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| 6.3. Test Method Validation (TMV)                                                                                                                         | No                                  | Yes                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br>The system does not utilize external measurement equipment and this change does not involve Operator influence.          |                                     |                          |
| 6.4. Operational Qualification (OQ)                                                                                                                       | No                                  | Yes                      |
| Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Based on the Risk Assessment, does an OQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br>100% critical to quality (CTQ) attributes verified.                                                                      |                                     |                          |

| 6.5. Performance Qualification (PQ)                                                                                                                      | No                                  | Yes                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Based on the Risk Assessment, does a PQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br>100% critical to quality (CTQ) attributes verified.                                                                     |                                     |                          |

**6.6. Electromagnetic Interference (EMI) Assessment:**

This change only affects test equipment; therefore, there is no impact to product EMI.

**7. IMPLEMENTATION ASSESSMENT:**

- This change is impacting production as spare part number 700011652 tested using the systems will not be able to ship (they will be quarantined) post the change being made until the functional testing is executed for all systems and the objective evidence is routed using the Validation Assessment Objective Evidence Routing Sheet.
- The functional tests will be run for spare part number 700011652 on each system and provided to Validation Engineering as objective evidence. The objective evidence shall be routed for approval using the Validation Assessment Objective Evidence Routing Sheet.

|                                                                                                                       |                            |
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**VALIDATION ASSESSMENT  
OBJECTIVE EVIDENCE COMPLETION**  
For the TE82882 – PDA Detector Final Station

**PREPARED BY**

| Name        | Role                 | Signature | Date |
|-------------|----------------------|-----------|------|
| Luo HuaZhen | Senior Test Engineer |           |      |

**REVIEWED BY**

| Name         | Role                    | Signature | Date |
|--------------|-------------------------|-----------|------|
| Eric Turner  | Principle Test Engineer |           |      |
| Chan Yee Hwa | Manufacturing Engineer  |           |      |

**APPROVED BY**

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| Tan Kah Chin | Senior Quality Assurance Manager |           |      |

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The below Attachments section is used to list all attachments that will serve as objective evidence, as required by this Validation Assessment Form.

**ATTACHMENTS:**

Attachment 1:

Attachment 2:

Attachment 3:

Attachment 4:

Attachment 5:

Attachment 6:

All Attachments shall be marked with the Validation Assessment Form Document Number, Attachment Number, and will be paginated, as applicable.