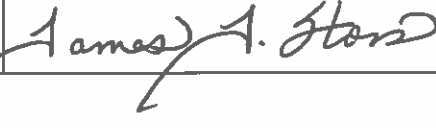
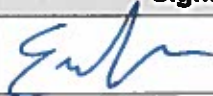


VALIDATION ASSESSMENT
For the TE82882 - PDA Detector Final Station

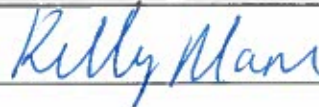
PREPARED BY

Name	Role	Signature	Date
James J. Stors	Senior Test Validation Engineer		10 JUN 2019

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principle Test Engineer		11 JUN 2019

APPROVED BY

Name	Role	Signature	Date
Kelly Mann	Quality Engineer II		11 Jun 2019

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.

The "Approved By" signature denotes that this document has been reviewed and approved for overall quality and completeness.

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 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, 800000202, 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. The system software is being revised to Version 4.2 to add part numbers 700012245, eLambda Optics Bench, and 700012243, 2998 Optics Bench Assembly. The software modifications are within the initialization sub-routine and does not affect the systems control or measurement routines.

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?	☒	☐

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?	☒	☐
Is the change due to firmware downloaded to the UUT by a test system?	☒	☐
Is the change a flash file update?	☒	☐
Is it a change to an existing, or the addition of a new, PCB Test Sequence?	☒	☐

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?	☒	☐

4.1.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, to a different facility?	☒	☐

4.2. Medium Risk Assessment

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

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

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 or end user due to the change.

6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

6.1. Equipment Design Verification (EDV)	No	Yes
Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?	☒	☐
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.)	☒	☐
Comments/Justification This change is due to adding part numbers that can be tested by the system using the existing software. The change does not affect the software, design or control of the system.		
6.2. Installation Qualification (IQ)	No	Yes
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.)	☐	☒
Comments/Justification A partial IQ of Test Script IQ-01 – Associated Documentation Verification, IQ-04 – Test Software and Instrument Firmware Version, and IQ-06 – Functional Verification shall be performed for TE82882-8, TE82882-9, TE82882-10, TE82882-11, TE82882-13, and TE82882-14 located in Flextronics contract manufacturing site of WPPL and TE82882-15 in Warranty and Repair. The functional test of IQ-06 shall be performed for the new part numbers defined in Section 4.1 to verify that the system control and measurement has not been negatively affected, and that the system correctly identifies the test unit on the Test Record. For the functional test any part number may be used, if the required part number unit is not available, as the functionality and requirements are identical. The systems located in Flextronics shall be executed by WPPL and TE82882-15 shall be performed by Milford Operations.		

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.)

☒☐**Comments/Justification**

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?

☒☐

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.)

☒☐**Comments/Justification**

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?

☒☐

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.)

☒☐**Comments/Justification**

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:

- TSP 735001613 has been revised to reflect the new part numbers and is in the Ready state in SAP and shall be verified through the execution of Test Script IQ-01.
- This change is impacting production as parts 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 the two (2) new part numbers 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.