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VALIDATION ASSESSMENT
For the TE82969 – PDA/2998 Linearity Test System

PREPARED BY

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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 TE82969 PDA/2998 Linearity Test System.

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/2998 Linearity Test System (TE82969). 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 PDA/2998 Linearity Test System, TE82969, is used to verify that linearity of PDA Detectors of the following part numbers is within specification: 186015026, 186002998, 186015032, 186015033, 186015030, 186299800, 186017003, 186017013, 186015034, and 186015053 as well as the spares and refurbished equivalent parts as listed in the PDA Final Test TSP 735001613 or the UPC2 PDA Detector and Veyron PDA Detector Final Test Procedure 735002531. Note that not all part numbers have a refurbished equivalent or spare. After the UUT has completed the firmware download according to the corresponding procedure and has passed the linearity test at TE82969, it is moved to the 2998 Final Test System (TE82882) to test noise, drift, and optics.

3. DESCRIPTION OF CHANGE

3.1. The system software is being revised to Version 2.2 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 TE82969-1 located in Flextronics contract manufacturing site of WPPL and TE82969-2 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. TE82969-1 shall be executed by WPPL and TE82969-2 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.
- 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.