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Document # TE83057-06JUL2018-VAF	SAP # TE0083057QX \ ECR # 9222852

VALIDATION ASSESSMENT
For the PDA Detector Download Station (TE83057)

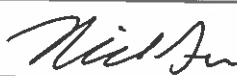
PREPARED BY

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

The "Reviewed By" signature denotes agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the equipment.

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 Download Station (TE83057). 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 Detector Download Station (TE83057) is used to download instrument firmware to the following part numbers: 186002998, 186015026, 186015030, 186015032, 186015033, 186017003, 186017013, 186020003, 186299800, 279002655, 700002787, 700004035, 700005424, 700005427, N2971013, and N2971035 as well as the refurbished equivalent part numbers as listed in the PDA Final Test TSP 735001613, Rev. U, Ver. 19. After the instrument firmware download is complete, the UUT is moved to the PDA / eLambda Linearity Test System (TE82969) to undergo wavelength calibration, then to the 2998 Final Test System (TE82882) to test noise, drift, and optics.

3. DESCRIPTION OF CHANGE

The following firmware updates are being implemented according to ECR # 9222852:

Table One: TE83057 Firmware Version Updates

Part Number	Current Firmware Version	New Firmware Version
186015032	1.69.6347	1.70.6367
186015033	1.69.6347	1.70.6367
186017003	1.65.6205	1.70.6363
186017013	1.65.6205	1.70.6363
186299800	1.41.6164	1.70.6363
186002998	1.41.6164	1.70.6363

This ECR impacts only the firmware file being loaded to the UUT, as controlled through a .txt file. This change does not affect the equipment software and does not affect the format or methods used for functional testing.

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 high Risk Assessment and the associated requalification requirements, as detailed in Section 6.0.

5. HAZARD ASSESSMENT:

No hazards are potentially introduced to the environment, operator, assembler, service technician, or end user.

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

Test software is not affected by this change and will remain at version 1.4. This change only affects the firmware file being loaded by the test software as controlled through a .txt file.

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 will be performed for TE83057-2 located in Milford Warranty and Repair and for TE83057-4 located at the Flextronics Contract Manufacturer Site in Singapore using Test Script IQ-04: Test Software and Instrument Firmware Version and Test Script IQ-06: Functional Verification. The functional tests will be performed with each of the following part numbers: 186015032, 186015033, 186017003, 186001713, 186002998, 186299800. Changes to firmware will not affect Test Scripts IQ-01: Associated Documentation Verification, IQ-02: Site Verification, IQ-03: Instrumentation Calibration Verification, or IQ-05: General Safety and Alarms. TE83057-1 and TE83057-3 located in Milford Production are not affected by this change because these part numbers are not built or tested at this site.		

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 This test system does not utilize an external measurement device and is not subject to operator induced variation. This change does not require a TMV as defined in the Process Validation Procedure 730001835.		

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 This change does not require an OQ as defined in the Process Validation Procedure 730001835 because 100% of critical to quality attributes are 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 This change does not require a PQ as defined in the Process Validation Procedure 730001835 because 100% of critical to quality attributes are verified.		

6.6. Electromagnetic Interference (EMI) Assessment:

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

7. IMPLEMENTATION ASSESSMENT:

- There is no impact to documentation, calibration or facilities/utilities.
- There is high impact on production schedules for TE83057-4 as no product can be shipped until qualification is complete. There is no impact on production schedules for TE83057-2.
- The changes will be implemented by the system owner and qualification will be performed by a Milford Validation Engineer or Singapore personnel as appropriate using pre-approved Installation Qualification Protocol 730004135.
- No additional training will be required.