

For the PCM II Tester (TE82817-2)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		16 Mar 2021

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

REVIEWED BY

Name	Role	Signature	Date
Matt Brule	Principal Test Engineer		30 MAR 2021

The "Reviewed By" signature[s] denotes agreement with the details of the planned testing and/or deliverables to be performed.

APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		31.Mar.2021

The "Approved By" signature denotes that this system change risk assessment and resulting planned process validation activities has been approved.

1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the Pump Control Module, PCM II Tester (TE82817-2), and to define the resulting deliverable(s) required to maintain the system process validation.

2. BACKGROUND

The PCM II Tester (TE82817-2), facilitates the functional test of the following part numbers: 186002449, 800000178, 279001290, 800000224. The system downloads firmware and verifies the electrical and mechanical functionality of the unit under test. Upon completion, a Final Test Record is automatically generated and printed for the operator to collect.

3. DESCRIPTION OF CHANGE

The computer in use at the PCM II Tester (TE82817-2) located in CEI Singapore has been replaced with a new PC. The new computer uses the same operating system, Windows XP, and there was no change to the custom test software. This change does not affect TE82817-1 located in Milford NPI.

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 local site?	☒	☐

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

5. HAZARD ASSESSMENT:

There are no hazards potentially introduced to the environment, operator, assembler, service technician or end user due to this 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?	☒	☐
Comments/Justification An EDV is not required because this change does not affect the way the system controls or measures a specification or PSC result.		

6.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change?	☐	☒
Comments/Justification A functional test will be performed on the PCM II Tester (TE82817-2) located in CEI Singapore to verify the custom test software and instrument firmware versions, as well as to verify the functionality of the system. In lieu of a formal IQ Report, the objective evidence will be attached to the provided Objective Evidence Completion form and submitted for approval.		

6.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change?	☒	☐
Comments/Justification TMV is not required because this 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 An OQ is not required 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 A PQ is not required 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 no impact to any other qualified, verified, or validated process, test method, or equipment.
- The production schedule for this system is currently stopped awaiting validation.
- This change will be implemented by Test Engineering; the qualification activities will be executed by a Test Engineer.
- No additional training be required.
- Product used for qualification or tested prior to approval of qualification activities shall be quarantined.
- Should any predefined deliverable to unable to be obtained the deviation should be addressed as an additional attachment to the Objective Evidence Completion Form.

**VALIDATION ASSESSMENT
OBJECTIVE EVIDENCE COMPLETION**
For the PCM II Tester (TE82817-2)

PREPARED BY

Name	Role	Signature	Date

The "Prepared By" signature denotes that the document accurately provides the required objective evidence.

REVIEWED BY

Name	Role	Signature	Date

The "Reviewed By" signature[s] denotes agreement that the required objective evidence is provided and accurate.

APPROVED BY

Name	Role	Signature	Date

The "Approved By" signature denotes that the objective evidence has been reviewed and approved for overall quality and completeness.

ATTACHMENTS:

Attachment 1: Cover sheet of the test procedure listing the custom test software version

Attachment 2: BOM for the unit under test listing the required firmware version

Attachment 3: Operator training record

Attachment 4: Passing Test Record