

 Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document #: TE82817-26SEP19-VAF	SAP #: TE0082817QX

VALIDATION ASSESSMENT
For the TE82817 – PCM II Final Test Station

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 TE82818 – TCM II Final Test Station.

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

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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 TE82817 – PCM II Final Test Station (TE82817). 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 PCM II Final Test Station, TE82817, is used to verify functionality of the Temperature Control Module II at Waters Singapore Contract Manufacturing site Venture Singapore.

The TE82817 test station is capable of testing the following Waters LC Part Numbers per the associated TSP:

TSP 735000888: 186002449, 800000178, 279001290, 800000224

3. DESCRIPTION OF CHANGE

3.1. Transfer of Functional Tester TE82817 from Venture Singapore to CEI Singapore. Requalification is required for this equipment transfer.

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:

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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 potentially introduced 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 a physical move and does not affect the 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 Full IQ shall be performed.		

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.)	☒	☐

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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 735000887 is not required to be revised as this change is only physically move the tester from Venture Singapore to CEI Singapore.
- The affected products will be stopped for shipping before this validation complete.
- The tester will be transferred from Venture Singapore to CEI Singapore and the relevant personnel will be trained after transfer.