

For the PCM II Tester (TE82817)

PREPARED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer	(See email dated 25 August 2020)	

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

REVIEWED BY

Name	Role	Signature	Date
Mark Jussaume	Senior Test Engineer	(See email dated 25 August 2020)	

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
Ashley Deschenes	Principal Operations Quality Engineer	(See email dated 26 August 2020)	

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

Emma Pierce

From: Mark Jussaume
Sent: Tuesday, August 25, 2020 13:52
To: Emma Pierce
Subject: RE: Review of TE82817-25AUG2020-VAF.docx
Attachments: TE82817-25AUG2020-VAF.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Looks good.

This email serves as my digital signature according to TMD010801.

Mark Jussaume
Sr. Test Engineer



[T] 508-482-2312
[F] +1 508 482 3373
[W] www.waters.com
[E] mark_jussaume@waters.com

Waters Corporation
34 Maple Street
Milford
MA 01757
USA



From: Emma Pierce <Emma_Pierce@waters.com>
Sent: Tuesday, August 25, 2020 1:08 PM
To: Mark Jussaume <Mark_Jussaume@waters.com>
Subject: Review of TE82817-25AUG2020-VAF.docx

Hi Mark,

Attached is TE82817-25AUG2020-VAF for your review. Please let me know if you have any comments or questions!

This email serves as my digital signature according to TMD010801.

Thanks,
Emma

Emma Pierce
Test Validation Engineer
Waters Corporation

phone 508.482.2452 **mobile** 201.264.1608
web www.waters.com **email** emma_pierce@waters.com
34 Maple Street, Milford, MA 01757 USA
[facebook](#) | [linkedin](#) | [twitter](#) | [youtube](#)

Emma Pierce

From: Ashley Deschenes
Sent: Wednesday, August 26, 2020 13:19
To: Emma Pierce
Subject: RE: TE82817-25AUG2020-VAF.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Emma,

Thanks for the quick turn around- I approve this revision.

Have a great weekend!

From: Emma Pierce <Emma_Pierce@waters.com>
Sent: Wednesday, August 26, 2020 1:16 PM
To: Ashley Deschenes <Ashley_Deschenes@waters.com>
Subject: TE82817-25AUG2020-VAF.docx

Hi Ashley,

Here is the latest revision for your approval.

Thanks,
Emma

Emma Pierce
Test Validation Engineer
Waters Corporation

phone 508.482.2452 **mobile** 201.264.1608
web www.waters.com **email** emma_pierce@waters.com
34 Maple Street, Milford, MA 01757 USA
[facebook](#) | [linkedin](#) | [twitter](#) | [youtube](#)

1. PURPOSE

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

2. BACKGROUND

The PCM II Tester (TE82817) 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 (TE82817-1) located in Milford NPI 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 TE82817-2 located at the Venture Contract Manufacturing Site in Singapore.

Approval of this document while personnel are working remotely is to adhere to TMD010801.

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?	☒	☐

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 (TE82817-1) located in Milford NPI 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 A 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 Validation 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 be unable to be obtained the deviation shall be addressed as an additional attachment to the Objective Evidence Completion Form.

**VALIDATION ASSESSMENT
OBJECTIVE EVIDENCE COMPLETION**
For the PCM II Tester (TE82817-1)

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