

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
Luo HuaZhen	Senior Test Engineer		01 Apr 2021

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

REVIEWED BY

Name	Role	Signature	Date
Matt Brule	Principal Test Engineer		

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

APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		

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

DOCUMENT TITLE: **PCM II FINAL TEST PROCEDURE**

SYSTEM/ASSEMBLY NAME: **PUMP CONTROL MODULE II, SYSTEM FLUIDICS ORGANIZER**

PART NUMBER AFFECTED **186002449, 800000178, 279001290, 800000224**

TEST EQUIPMENT NAME: **PCM II FINAL TEST STATION**

TEST EQUIPMENT NUMBER: **TE82817**

TEST SOFTWARE:



AUTHOR(S): **MARK JUSSAUME**

DATE: **January 21, 2004**

REVISED BY: **MARK JUSSAUME**

DATE: **April 27, 2017**

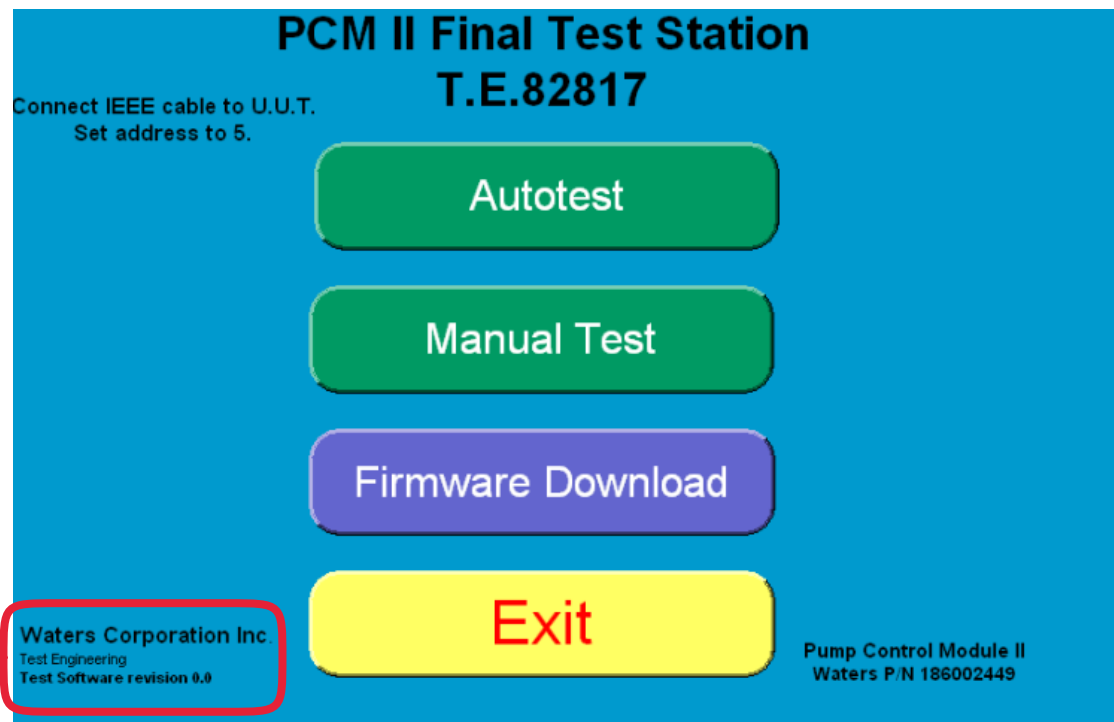
Document No.: TE82817-2-16MAR2021-VAF

Iteration No.: N/A

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Document # **TE82817-25AUG2020-VAF**

Attachment # **1** Page **1** of **2**



Document No.: TE82817-2-16MAR2021-VAF

Iteration No.: N/A

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Display material BOM: General Item Overview

Waters
THE SCIENCE OF WHAT'S POSSIBLE.

Subitems

New Entries

Header

Validity

Material

186003765

System Fluidics Organizer

C

Plant

CRDE

Waters Single Design Plant

Alternative BOM

1

Material

Document

General

Item	ICt	Component	Component description	Qu
0010	L	279001290	ORGANIZER, SYSTEM FLUIDICS	1
0020	L	200001290	STARTUP KIT, SYSTEM FLUIDICS ORGANIZER	1
0040	L	WAT006277	LABEL, CONGRATULATIONS	1
0050	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1
0060	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1
0080	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	1
0090	L	290000870	BOX, SHIPPING, SYSTEM FLUIDICS ORGANIZER	1
0100	L	716002119	Information Set, Sys. Fluidics Org.	1
0110	L	361000278	System Fluidics Organizer Firmware v2.00	1
0120	L	361000223	Pump Control Module II FW, v3.00	1

Position...

Initial

Entry

1 / 10

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Iteration No.: N/A

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TRAINING CERTIFICATION FORM

Product: 186002441 TCM II / 186002449 PCM II

Date: 19 NOV 2019

Document No	Document Name	Revision	Verified Signature/Date
279000691	ASSY, TCM II	H	Jason Wang / 20 Nov 2019
186002441	ASSY, TCM II (PACKING)	A	Jason Wang / 22 Nov 2019
735000888	TCM II FINAL TEST PROCEDURE	E	Jason Wang / 20 Nov 2019
WAT046538	GENERIC HI-POT & GND CONT Test PROC.	12	Jason Wang / 20 Nov 2019
WA-6170-WI-001	200000194 TCM II STARTUP KIT	00	Jason Wang / 22 Nov 2019
279000632	ASSY, PCM II	G	Jason Wang / 21 Nov 2019
186002449	ASSY, PCM II (PACKING)	A	Jason Wang / 22 Nov 2019
735000887	PCM II FINAL TEST PROCEDURE	G	Jason Wang / 21 Nov 2019
WA-6180-WI-001	200000193 PCM II STARTUP KIT	00	Jason Wang / 22 Nov 2019

	Name	Signature	Date
Trainee	Alex EE		22 Nov 2019
Master Trainer	Jason Wang		22 Nov 2019
Manufacturing Manager	Koh Choon Hoe		22 Nov 2019

Document No.: TE82817-2-16MAR2021-VAF

Iteration No.: N/A

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Waters Corporation

INSTRUMENT FINAL TEST RECORD

Part Number:	186002449	Description:	Pump Control Module II
Tested By:	Alex EE	Date:	4/1/2021 11:13:18 AM
Serial Number:	M18PC2543G	Control Number:	N/A
Software Revision:	4.00 Build#: 12 (Oct 15 2008)	Factory Order:	1234567

- 1) Hi - Pot / Ground Continuity Test PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 2) Rear Panel I/O Test PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 3) Pumps A, B, & C Status Test
(-12 VDC & +12 VDC) PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 4) Pumps A, B, & C Pressure Test
(-10 VDC - 0 VDC) PASS ☒ FAIL ☐ see note # _____ PASS ☐
- 5) Pumps A, B, & C Control Test
(0 - 2133 HZ TTL) PASS ☒ FAIL ☐ see note # _____ PASS ☐

Instrument Result: PASS ☒ FAIL ☐ Signed:  Date: 01/APR/2021

Notes:

N/A

Document No.: TE82817-2-16MAR2021-VAF

Iteration No.: N/A

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This Test Record and any data contained within it are proprietary to Waters Corporation and must be retained by Waters for the time period prescribed in its Quality Records Retention Policy. If any of the individual tests noted above fail; a note must be referenced that details the work performed to correct that specific deficiency. An overall failure indicates a special circumstance in which case a complete retest is to be done. A second form is required to document that testing; the initial form must be attached and retained.