

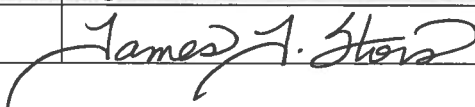
Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE82817-1-IQR	Iteration No: 00	SAP No: TE0082817QX	

INSTALLATION QUALIFICATION REPORT
For the PCM II Final Test Station (TE82817-1)

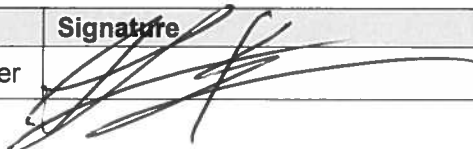
PREPARED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		29 Jun 2017

REVIEWED BY

Name	Role	Signature	Date
James Stors	Senior Test Validation Engineer		29 JUN 2017

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		29 June 2017

The "Prepared By" signature denotes that this document accurately describes the qualification activities.

The "Reviewed By" signature[s] denotes agreement with the description of the qualification activities.

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

REVISION HISTORY

Version	Author	Summary of change
00	Emma Pierce	First document for approval

 THE SCIENCE OF WHAT'S POSSIBLE™	Installation Qualification Report		
Report No: TE82817-1-IQR	Iteration No: 00	SAP No: TE0082817QX	

1.0 Purpose

The PCM II Final Test Station (TE82817-1) is located in the NPI laboratory in Milford, MA. The station is used to perform the final instrument test of the following part numbers: 186002449 and 279001290. The Test Station has two versions of the test software which are identical in functionality. The PCM II Software tests the PCM II (Part #186002449, Refurb. Part #800000178) and the SFO Software tests the PCM II sub-assembly (Part #279001290, Refurb. Part #800000224).

In the final test, the UUT is connected to the test station and the performance of the rear panel I/O, the pump status, pump pressure, and pump control is verified to operate within design specifications. When complete, a hard copy of the final test record is printed.

This Installation Qualification is being performed as required by the Quality Plan #2017-002.

2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the PCM II Final Test Station (TE82817-1) based on the requirements of the Installation Qualification Procedure, 730004135 Ver. 00.

This Installation Qualification Report defines the documents used to qualify the PCM II Final Test Station (TE82817-1).

3.0 Summary of Results - Statement of Fitness for Intended Use

The PCM II Final Test Station was tested in accordance with the Installation Qualification Procedure, 730004135 Ver. 00. All Test Scripts were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the PCM II Final Test Station complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the PCM II Final Test Station (TE82817-1) can be considered fully qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
TSP	Test Specification and Procedure
CAL/PM	Calibration/Preventive Maintenance
NPI	New Product Introduction
UUT	Unit Under Test
S/N	Serial Number
P/N	Part Number
SFO	System Fluidics Organizer
PCM II	Pump Control Module II
N/A	Not Applicable

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5.0 Training

The operator of the PCM II Final Test Station (TE82817-1) is the executor of this qualification, and was trained according to the PCM II Final Test Procedure, 735000887, Ver. 06 and the Installation Qualification Procedure, 730004135, Ver. 00. Refer to Attachments 7.16 and 7.17 for the training records.

6.0 Qualification Results

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.1.

6.1.1 The PCM II Final Test Procedure, 735000887, Ver. 06, was confirmed to be in SAP with a status of Release General, as evidenced below.

Document List After Selection 7 Hits									
									
Rev	Type	Document	Vr	Description	From date	Change No.	Status text	Complete name	Effectivity Date
A	TSP	735000887	00	PCM II Final Test Procedure	05/03/2004	9108646	RELEASE GENERAL	Mark Jussauime	
B	TSP	735000887	01	PCM II Final Test Procedure	10/20/2004	9111529	RELEASE GENERAL	Mark Jussauime	
C	TSP	735000887	02	PCM II Final Test Procedure	01/12/2005	9113219	RELEASE GENERAL	Chris Green	
D	TSP	735000887	03	PCM II Final Test Procedure	12/11/2006	9125792	RELEASE GENERAL	Mark Jussauime	
E	TSP	735000887	04	PCM II Final Test Procedure	11/12/2014	9193031	RELEASE GENERAL	Mark Jussauime	
F	TSP	735000887	05	PCM II Final Test Procedure	06/10/2016	9207397	RELEASE GENERAL	Matt Brule	
G	TSP	735000887	06	PCM II Final Test Procedure	05/24/2017	9215744	RELEASE GENERAL	Mark Jussauime	

6.1.2 The TE82817-1 PM Procedure, 735002828, Ver. 00, was confirmed to be in SAP with a status of Release General, as evidenced below.

Document List After Selection 1 Hits									
									
Rev	Type	Document	Vr	Description	From date	Change No.	Status text	Complete name	Effectivity Date
A	CAL	735002828	00	TE82817 PM Procedure	01/30/2013	9176534	RELEASE GENERAL	Mark Jussauime	

6.2 Test Script IQ-02: Site Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.2.

6.2.1 The ambient temperature and humidity were measured using an Extech 445703 Hygro-thermometer, ID#95648, and was determined to be within specification as defined by Performance Specification, PCB, Pump Control WAT200454, Ver. 00. The calibration record is provided as Attachment 7.3.

6.2.2 The electrical supply was measured using a Fluke 189 Multimeter, ID#98209, and was determined to be within specification as defined by Performance Specification, PCB, Pump Control WAT200454, Ver. 00. The calibration record is provided as Attachment 7.4.

6.2.3 The Test Station was confirmed to have more than the three (3) dedicated electrical outlets required.

6.2.4 The space and test bench of the PCM II Final Test Station (TE82817-1) were confirmed to have adequate space for testing and service. The bench was confirmed to be large and strong enough to support all test equipment. A picture of the Test Station work area is provided as Attachment 7.5.

6.2.5 The Test Station was confirmed to have one (1) network available.

6.3 Test Script IQ-03: Instrumentation Calibration Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed script is provided as Attachment 7.6.

6.3.1 The PCM II Final Test Station (TE82817-1) was confirmed to be in the Calibration Manager Database with a twelve (12) month maintenance cycle.

6.3.2 The Test Station was confirmed to have had preventative maintenance within this time frame. A screen capture of the PCM II Final Test Station (TE82817-1) from the Equipment Master Database is provided as Attachment 7.7.

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- 6.4 Test Script IQ-04: Test Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.8.
- 6.4.1 The Test Equipment Software version listed in PCM II Final Test Procedure 735000887, Ver. 06 is Test Software 0.0 and was verified to match the version listed in the Test Equipment program displays of the PCM II Test Program and the SFO Test Program. A screen capture of the program displays are provided as Attachments 7.9 and 7.10, respectively.
- 6.4.2 The PCM II Firmware version listed in Production Master PCMI 361000331, Ver. 00 is Firmware v4.00 and was verified to match the version listed in the Loader Dialog Box. A screen capture of the program is provided as Attachment 7.11.
- 6.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.12.
- 6.5.1 It was confirmed that there were no mechanical safety pinch points or sharp edges.
- 6.5.2 The PCM II Final Test Station was confirmed to pass an Electrical Safety Hi-Pot/Ground Continuity test. The calibration record is provided as Attachment 7.13.
- 6.6 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.14.
- 6.6.1 One (1) UUT Part #186003765 (Serial #F17APS843M) containing the sub-assembly Part #279001290 was tested using the PCM II Final Test Station (TE82817-1) SFO program with all tests passing. The final test record is provided as attachment 7.15.
- 6.7 This table provides a summary of each test script as performed according to 7300004135 Ver. 00 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.1	None
IQ-02	Pass	Attachments 7.2, 7.3, 7.4, and 7.5	None
IQ-03	Pass	Attachments 7.6 and 7.7	None
IQ-04	Pass	Attachments 7.8, 7.9, 7.10, and 7.11	None
IQ-05	Pass	Attachments 7.12 and 7.13	None
IQ-06	Pass	Attachments 7.14 and 7.15	None

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE82817-1-IQR	Iteration No: 00	SAP No: TE0082817QX	

7.0 Attachments

- 7.1 Completed Test Script IQ-01: Associated Document Verification
- 7.2 Completed Test Script IQ-02: Site Verification
- 7.3 Objective Evidence IQ-02: Extech 445703 Hygo-thermometer (ID#95648) Calibration Record
- 7.4 Objective Evidence IQ-02: Fluke 189 Multimeter (ID#98209) Calibration Record
- 7.5 Objective Evidence IQ-02: Photo of Test Station Work Area
- 7.6 Completed Test Script IQ-03: Instrument Calibration Verification
- 7.7 Objective Evidence IQ-03: PCM II Final Test Station (TE82817-1) Calibration Record
- 7.8 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.9 Objective Evidence IQ-04: Screen Capture of PCM II Test Equipment Software
- 7.10 Objective Evidence IQ-04: Screen Capture of SFO Test Equipment Software
- 7.11 Objective Evidence IQ-04: Screen Capture of Test Equipment Firmware
- 7.12 Completed Test Script IQ-05: General Safety and Alarms
- 7.13 Objective Evidence IQ-05: Hi-Pot Ground Continuity Tester (ID#90265) Calibration Record
- 7.14 Completed Test Script IQ-06: Functional Verification of UUT Part #186003765 (279001290)
- 7.15 Objective Evidence IQ-06: Instrument Final Test Record for UUT Part #186003765
- 7.16 Completed Operator Training Record 735000887 Ver. 06
- 7.17 Completed Executor Training Record 730004135 Ver. 00

8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the Installation Qualification Procedure 730004135 Ver. 00.

9.0 References

The current approved versions of the following documents are referenced within this document:

Document Number	Document title
730004135 Ver. 00	Installation Qualification Procedure
735000887 Ver. 06	PCM II Final Test Procedure
735002828 Ver. 00	TE82817-1 PM Procedure
WAT200454 Ver. 00	Performance Spec, PCB, PMP Control
WAT046538 Ver. 09	Generic Electrical Safety Test Procedure
735001477 Ver. 05	Serial Number Log, SFO
361000331 Ver. 00	Pump Control Module II Recreate Procedure v4.00.12
2017-002	Legacy Products Relocation Quality Plan

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 4 of 11

IQ Test name: Associated Documentation Verification		Test Script No.: IQ-01
Equipment No./ID: TE82817-1	Equipment Name: PCM 11 Final Test Station	

Installation Site: NPI, Milford, MA

Purpose:

To verify that supporting documentation is available prior to the completion of qualification.

Test execution:

List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header and then complete the table below. If applicable documents are unavailable state why in the comments section. All applicable documents must be in either Ready, Pre-Rel-Prod, or Release General state in SAP. Enter N/A for any parameter or cell that is not used or not applicable.

Objective evidence:

Completed Test Script Data Sheet

SAP Screen shot of below available document(s)

Document Type	Title; Doc. No.; Revision/Version No.	Status in SAP	Initial & Date
TSP	PCM 11 Final Test Procedure 735000887 Ver 06	Release General	Eep 20 Jun 2017
CAL	TE82817 PM Procedure 735002828 Ver 00	Release General	Eep 20 Jun 2017
N/A Eep 21 Jun 2017			

Comments:

N/A Eep 21 Jun 2017

Overall Test Conclusion: ☒ Pass ☐ Fail

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Iteration 00

Document No.: TE0082817-1-IQK

Attachment: 7.1 Page: 1 of 1

IQ Test name: Site Verification			Test Script No.: IQ-02	
Equipment No./ID: TE 82817-1		Equipment Name: PCM11 Final Test Station		
Installation Site: NPI, Milford, MA				
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test execution: List any additional applicable environmental parameters in the Parameters column. Using the applicable equipment documentation, define the specifications in the Acceptance Criteria column, as appropriate. Verify and/or measure the applicable parameters and complete the table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable. Objective evidence: Completed Test Script Data Sheet. Photo(s) of the work area, if applicable. Copies of calibration certificates for gauges or meters used for measurement, if applicable.				
Parameters	Acceptance criteria	As found	Pass/Fail	Initial & Date
Ambient Temperature	0° - 40°	23.3°C	Pass	Exp 20 Jun 2017
Relative Humidity	20%-80% non condensing	50%	Pass	Exp 20 Jun 2017
Workspace	Adequate free space for testing and service	Adequate space	Pass	Exp 20 Jun 2017
Test Station Bench	Large and sturdy enough to hold equipment	Large and sturdy enough	Pass	Exp 20 Jun 2017
Electrical Supply	105-129 VAC / 60Hz	115.72 VAC / 60.01 Hz	Pass	Exp 20 Jun 2017
Electrical Outlets	≥ 4	10	Pass	Exp 20 Jun 2017
Network Available	≥ 1	1	Pass	Exp 20 Jun 2017
N/A Exp 27 Jun 2017				
Comments: Temp and humidity specified in WAT200454 Ver. 00 ↳ Recorated with Asset# 95648 (Calibrated 15 Nov 2016) Electrical Supply specified in WAT200454 Ver. 00 ↳ Recorated with Asset# 98209 (Calibrated 20 Dec 2016)				
Overall Test Conclusion:		☒ Pass ☐ Fail		

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.
HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Iteration 00

Document No.: TE0082817-1-100R

Attachment: 7.2 Page: 1 of 1

CERTIFICATE OF CALIBRATION

ISSUE DATE: 11/15/2016 Certificate #: 1418362

CUSTOMER / LOCATION WATERS CORPORATION - 6 @ 34 MAPLE STREET MILFORD, MA 01757	EQUIPMENT INFORMATION MANUFACTURER: EXTECH MODEL NO: 445703 SERIAL NO: N/A CONTROL NO: 95648 TYPE: THERMOHYGROMETER
--	---

DEPT: WP72 PURCHASE ORDER: ECL#11/7/2016	Remarks: IN LAB
---	---------------------------

METHOD / ENVIRONMENT

PERFORMED: IN LAB	TEMPERATURE (deg C): 24.1
METHOD: ECP NO. 1.3.20 Rev.7	REL HUMIDITY (%RH): 23.6

CALIBRATION

CALIBRATION DATE: 15/Nov/2016	METROLOGIST: <i>[Signature]</i>
CALIBRATION DUE: 30/Nov/2017	

Standards Used To Calibrate Equipment	Type Equipment	Report No.	Last Cal. Date	Cal. Due Date
I.D. Template 52564 @ THUNDER SCIENTIFIC 2500-LT	HUMIDITY GENERATOR	1377480	08/17/2016	02/26/2017

The ESSCO Quality System is accredited to ISO 17025:2005

The results above relate only to the item(s) calibrated. Expanded uncertainties were calculated per ISO "Guide to the Expression of Uncertainty Measurement", (GUM) with 95% confidence level and a coverage factor of k=2. This certificate shall not be reproduced, except in full, without written approval of ESSCO. The user should consider the measurement uncertainty when assessing the metrological status of the equipment. This document certifies that the unit performed to applicable specifications upon successful completion of the calibration. Any number of factors may cause the calibration item to drift out of calibration before the recommended interval has expired. The standards used are traceable to NIST or a National Measurement Institute.

This calibration was performed in compliance with the ESSCO Quality System manual, ECL1 Rev 36, dtd 16 Dec 2015, ISO 9001:2008, ANSI/NCISL Z540.1, ISO 10012:2003, ISO 13485, TS 16949, and when required contractually, 10CFR21 and 10CFR50 App B.

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government.

Internal Use Only: 11/07/2016 11/15/2016 DATA EOM WAT120 ESSCO VAN 2 166704

NICHOLAS PAOLETTA
 Releasing Authority

Document No.: TE0082877-10
 Attachment: 7.3 Page: 1 of 2
 Iteration 00

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
1	TEMPERATURE	25.0	26.0 24.0	° C	25.6	25.6	0.091°C
2	HUMIDITY	30	35 25	% RH	32	32	0.82% RH
3	HUMIDITY	50	55 45	% RH	45	45	0.82% RH
4	HUMIDITY	80	85 75	% RH	75	75	0.82% RH

End of Data

Note: A = Adjusted F = Failed L = Limited

Iteration 00

Document No.: TE0082817-1-108

Attachment: 7.3 Page: 2 of 2

CERTIFICATE OF CALIBRATION

ISSUE DATE: 12/20/2016 Certificate #: 1432411

CUSTOMER / LOCATION WATERS CORPORATION - 5 @ 34 MAPLE STREET DEPT TE MILFORD, MA 01757 DEPT: WP72 PURCHASE ORDER:	EQUIPMENT INFORMATION MANUFACTURER: FLUKE MODEL NO: 189 SERIAL NO: 91000013 CONTROL NO: 98209 TYPE: DMM
---	---

AS FOUND AS LEFT	IN TOLERANCE IN TOLERANCE	Remarks: ON SITE
-----------------------------------	--	---------------------

METHOD / ENVIRONMENT PERFORMED: ON SITE METHOD: FLUKE 187/189	CALIBRATION CALIBRATION DATE: 20/Dec/2016 METROLOGIST: B. Bunnell CALIBRATION DUE: 31/Dec/2017
--	--

Standards Used To Calibrate Equipment I.D. Template E3434 @ FLUKE 5522A-OPT SC1100	Type Equipment CALIBRATOR	Report No. 1370078	Last Cal. Date 08/01/2016	Cal. Due Date 09/01/2017
--	------------------------------	-----------------------	------------------------------	-----------------------------

Document No.: TE 0082817-1-10
 Attachment: 7.4 Page: 1 of 1

The ESSCO Quality System is accredited to ISO 17025:2005

The results above relate only to the item(s) calibrated. Expanded uncertainties were calculated per ISO "Guide to the Expression of Uncertainty Measurement", (GUM) with 95% confidence level and a coverage factor of k=2. This certificate shall not be reproduced, except in full, without written approval of ESSCO. The user should consider the measurement uncertainty when assessing the metrological status of the equipment. This document certifies that the unit performed to applicable specifications upon successful completion of the calibration. Any number of factors may cause the calibration item to drift out of calibration before the recommended interval has expired. The standards used are traceable to NIST or a National Measurement Institute.

This calibration was performed in compliance with the ESSCO Quality System manual, ECL1 Rev 36, dtd 16 Dec 2015, ISO/IEC 17025:2005, ISO 9001:2008, ANSI/NCSL Z540-1 part 1, ISO 10012:2003, ISO 13485, TS 16949, and when required contractually, 10CFR21 and 10CFR50 App. B.

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government.

Kevin R. Pistey

Kevin R. Pistey
 Releasing Authority

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
1	DCmV, 500mV RING	0.00	0.20 -0.20	mV	0.00	0.00	0.0067 mV
2	DCmV, 500mV RING	500.00	500.17 499.83	mV	499.98	499.98	0.035 mV
3	DCmV, 3000mV RING	2000.0	2001.0 1999.0	mV	1999.9	1999.9	0.13 mV
4	DCmV, 3000mV RING	-3000.0	-2998.7 -3001.3	mV	-2999.8	-2999.8	0.19 mV
5	DC VOLTAGE, 5V RING	0.0000	0.0010 -0.0010	V	0.0000	0.0000	0.000082 V
6	DC VOLTAGE, 5V RING	5.0000	5.0023 4.9977	V	4.9998	4.9998	0.00035 V
7	DC VOLTAGE, 5V RING	-5.0000	-4.9977 -5.0023	V	-4.9999	-4.9999	0.00035 V
8	DC VOLTAGE, 50V RING	-50.000	-49.982 -50.018	V	-49.998	-49.998	0.0038 V
9	DC VOLTAGE, 500V RING	-500.00	-499.48 -500.52	V	-499.99	-499.99	0.049 V
10	DC VOLTAGE, 1000V RING	-500.0	-499.3 -500.7	V	-500.0	-500.0	0.076 V
11	ACmV @ 100KHz, 50mV RING	2.500	2.915 2.085	mV	2.264	2.264	0.048 mV
12	ACmV @ 20KHz, 50mV RING	50.000	53.150 46.850	mV	48.207	48.207	0.081 mV
13	ACmV @ 100KHz, 50mV RING	50.000	57.540 42.460	mV	45.601	45.601	0.33 mV
14	ACmV @ 10KHz, 500mV RING	500.00	525.40 474.60	mV	482.49	482.49	0.24 mV
15	ACmV @ 20KHz, 3000mV RING	3000.0	3049.0 2951.0	mV	2982.1	2982.1	2.8 mV
16	ACmV @ 100KHz, 3000mV RING	3000.0	3244.0 2756.0	mV	2936.7	2936.7	10.3 mV
17	AC VOLTAGE @ 100KHz, 5V RING	0.2500	0.2740 0.2260	V	0.2368	0.2368	0.00089 V

Attachment: 7.4 Page: 2 of 5

Document No.: 7E0002817-1-10K

Revision: 00

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
18	AC VOLTAGE @ 20KHz, 5V RNG	5.0000	5.0790 4.9210	V	4.9762	4.9762	0.0076 V
19	AC VOLTAGE @ 100KHz, 5V RNG	5.0000	5.4040 4.5960	V	4.7627	4.7627	0.033 V
20	AC VOLTAGE @ 700Hz, 50V RNG	50.000	50.240 49.760	V	50.037	50.037	0.036 V
21	AC VOLTAGE @ 20KHz, 50V RNG	50.000	50.790 49.210	V	50.114	50.114	0.22 V
22	AC VOLTAGE @ 100KHz, 50V RNG	50.000	54.040 45.960	V	48.568	48.568	0.22 V
23	AC VOLTAGE @ 65Hz, 500V RNG	500.00	502.40 497.60	V	499.89	499.89	0.38 V
24	AC VOLTAGE @ 65Hz, 1000V RNG	500.0	506.0 494.0	V	499.9	499.9	0.38 V
25	FREQUENCY @ 1V	20.000	20.002 19.998	kHz	20.000	20.000	0.00058 kHz
26	DUTY @ 500Hz 2.2Vpp	30.00	38.18 21.82	%	27.88	27.88	0.0058%
27	AC+DC @ 20KHz 3000R	1000.0	1024.0 976.0	mV	997.9	997.9	0.99 mV
28	AC+DC @ 20KHz 50RNG	50.000	51.040 48.960	V	49.967	49.967	0.090 V
29	RESISTANCE, 500 ohm RNG	0.00	0.10 -0.10	Ohm	0.00	0.00	0.011 ohm
30	RESISTANCE, 500 ohm RNG	500.00	500.35 499.65	Ohm	499.99	499.99	0.12 ohm
31	RESISTANCE, 5 kohm RNG	5.0000	5.0027 4.9973	kohm	4.9991	4.9991	0.0012 kohm
32	RESISTANCE, 50 kohm RNG	50.000	50.027 49.973	kohm	49.987	49.987	0.012 kohm
33	RESISTANCE, 500 kohm RNG	500.00	500.27 499.73	kohm	499.90	499.90	0.15 kohm
34	RESISTANCE, 5 Mohm RNG	5.0000	5.0079 4.9921	Mohm	5.0047	5.0047	0.0041 Mohm
35	RESISTANCE, 30 Mohm RNG	30.000	30.304 29.696	Mohm	30.054	30.054	0.035 Mohm
36	RESISTANCE, 500 Mohm RNG	100.0	110.2 89.8	Mohm	99.9	99.9	0.59 Mohm
37	nS 50 RNG OPEN	0.00	0.10 -0.10	ns	-0.02	-0.02	0.0058 nS
38	nS 50 RNG 100 Mohm	10.00	10.20 9.80	ns	9.97	9.97	0.064 nS
39	DCµA, 500µA RNG	0.00	0.20 -0.20	µA	0.01	0.01	0.0058 µA

Attachment: 7/4 Page: 3 of 5

Document No: 1432411-1-18280001

Iteration: 00

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
40	DCµA, 500µA RING	500.00	501.45 498.55	µA	500.06	500.06	0.13 µA
41	DCµA, 500µA RING	-500.00	-498.55 -501.45	µA	-499.84	-499.84	0.13 µA
42	DCµA, 5000µA RING	5000.0	5012.7 4987.3	µA	4999.9	4999.9	0.64 µA
43	DCmA, 50mA RING	0.000	0.010 -0.010	mA	-0.001	-0.001	0.0039 mA
44	DCmA, 50mA RING	50.000	50.085 49.915	mA	50.015	50.015	0.0096 mA
45	DCmA, 50mA RING	-50.000	-49.915 -50.085	mA	-50.014	-50.014	0.0096 mA
46	DCmA, 400mA RING	-329.00	-328.49 -329.51	mA	-329.05	-329.05	0.042 mA
47	DC CURRENT, 5A RING	0.0000	0.0010 -0.0010	Amp	-0.0002	-0.0002	0.00039 A
48	DC CURRENT, 5A RING	5.0000	5.0260 4.9740	Amp	5.0010	5.0010	0.0038 A
49	DC CURRENT, 5A RING	-5.0000	-4.9740 -5.0260	Amp	-5.0018	-5.0018	0.0038 A
50	DC CURRENT, 10A RING	-6.000	-5.968 -6.032	Amp	-6.002	-6.002	0.0046 A
51	ACµA @ 1KHz, 500µA RING	500.00	503.95 496.05	µA	500.45	500.45	1.01 µA
52	ACµA @ 1KHz, 5000µA RING	1500.0	1511.8 1488.2	µA	1501.3	1501.3	2.08 µA
53	ACmA @ 1KHz, 500mA RING	2.500	2.539 2.461	mA	2.506	2.506	0.0033 mA
54	ACmA @ 10KHz, 400mA RING	329.00	334.04 323.96	mA	329.43	329.43	2.31 mA
55	AC CURRENT @ 1KHz, 5A RING	0.2500	0.2578 0.2422	Amp	0.2506	0.2506	0.00061 A
56	AC CURRENT @ 10KHz, 5A RING	0.2500	0.2690 0.2310	Amp	0.2541	0.2541	0.0021 A
57	AC CURRENT @ 1KHz, 10A RING	6.000	6.095 5.905	Amp	5.997	5.997	0.025 A
58	CAPACITANCE, OPEN <0.070 nF			CHECK	PASS	PASS	0.059 nF
59	CAPACITANCE, 110nF RING	100.0	101.5 98.5	nF	99.9	99.9	0.41 nF
60	CAPACITANCE, 1µF RING		5.10 4.90	µF	4.98	4.98	0.032 µF
61	DIODE 3.1V RING		1.1000 0.9000	V	1.0006	1.0006	0.00018 V

Attachment: 7.14 Page: 5 of 5

Document No.: TE0082817-1-10R

Iteration 00

00 non-compliant

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
62	TEMPERATURE, K TYPE	-10.0	-8.9 -11.1	° C	-9.8	-9.8	0.23°C
63	TEMPERATURE, K TYPE	0.0	1.0 -1.0	° C	0.2	0.2	0.23°C
64	TEMPERATURE, K TYPE	350.0	355.0 345.0	° C	350.3	350.3	0.33°C

End of Data

Note: A = Adjusted F = Failed L = Limited ** = Outside Scope of Accreditation

Document No.: TE 00828 17-1-10R Revision 00
Attachment: 74 Page: 5 of 5



Iteration 00
Document No.: TE0082817-1-10R
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Iteration 00
Document No.: TE0082817-1-1QR
Attachment: 7.4 Page: 1 of 1

4.2 TE82817-1

File Action Edit View Help

New

EQUIPMENT MASTER: TE82817-1

Identifier: TE82817-1

Component ID:

EQUIPMENT SUPPORT **SCHEDULING** HISTORY

Add Event Add Similar Remove Event

Event Name	Event Type	Due Date
12 Month	Maintenance	28 Feb 2018

Event Type: Maintenance

Event Name: 12 Month

View Audit Trail ... Add History for this Event

DATES DETAILS SUPPORT MAINTENANCE

Due Date: 28 Feb 2018

Future Due Date: 28 Feb 2019

Last Action Date: 28 Feb 2017

Basis for Date Calculation: Date of Event

Interval: Month (End of Month)

Number: 12

Reminder Date:

Reminder Days:

Scheduled Person:

Work Flow Template:

Iteration 00

Document No.: TE0082817-1-1QR

Attachment: 7.7 Page: 1 of 1

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 7 of 11

IOQ Test name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04	
Equipment No./ID: TE82817-1		Equipment Name: PCM II Final Test Station		
Installation Site: NPI, Milford, MA				
Purpose: To verify that the installed firmware/software is correct per the applicable design/operational documents (TSP, ASP, MPR, BOM, and/or other Design documents). Test execution: List all critical instruments/components and/or sub-systems that require software and/or firmware in the Description column. List the associated required software/firmware version, as defined in the applicable design/operational documents, in the Acceptance criteria column. Verify that the software/firmware version on the Test Equipment match the acceptance criteria and are identical. Enter N/A for any parameter or cell that is not used or applicable. Objective evidence: Completed Test Script Data Sheet Identify the applicable design/operational document that defined the required software/firmware version(s) in the associated Installation Qualification Report.				
Description	Acceptance criteria	As found	Pass/Fail	Initial & Date
Test Equipment Software PCM II	Version: 0.0	Version: 0.0	Pass	EE 23 Jun 2017
Test Equipment Software SFD	Version: 0.0	Version: 0.0	Pass	EE 23 Jun 2017
PCM II Firmware	Version: 4.00	Version: 4.00	Pass	EE 26 Jun 2017
	Version:	Version:		
	Version: N/A	Version:		
	Version:	Version:		
	Version:	Version:		
	Version:	Version:		
	Version:	Version:		

Comments:
Both software versions specified in 735000887 ver. 06
PCM II firmware specified in 361000331 ver 00

Overall Test Conclusion: ☒ Pass ☐ Fail

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Template 730000483 V06

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Iteration 00

Document No.: TE0082817-1-10R

Attachment: 7.8 Page: 1 of 1

PCM II Final Test Station

T.E.82817

Autotest

Manual Test

Firmware Download

Exit

Waters Corporation Inc
Test Engineering
Test Software revision 0.0

Pump Control Module II
Waters P/N 186002449

Iteration 00
Document No.: TE0082817-1-10R
Attachment: 7.9 Page: 1 of 1

PCM II Final Test Station

T.E.82817

Autotest

Manual Test

Firmware Download

Exit

Waters Corporation Inc.

Test Engineering

Test Software revision 0.0

System Fluidics Organizer

Waters P/N 186003765

Start



SFO TE82817



2:14 PM

Iteration 00
Document No.: TE 0082817-1-10R
Attachment: 7.10 Page: 1 of 1

Step 4 -> Select the file to load

Waters Firmware Update

C:\Program Files\TE82817\Pump Control Module.sft

Browse...

The selected file contains firmware for:

Waters PCM II v4.00

Checksum: 0x9AF94C9E

< Back

Next >

Cancel

Iteration 00
Document No.: TE0082817-1-1 DR
Attachment: 7-11 Page: 1 of 1

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IOQ Test name: General Safety and Alarms		Test Script No.: IQ-05	
Equipment No./ID: TE82817-1		Equipment Name: PCM II Final Test Station	
Installation Site: NPI, Milford, MA			
Purpose: To verify that the test equipment can operate in a safe manner, within its designated location.			
Test List any additional safety related conditions or alarms in the Safety Inspection column. List the associated safety requirement/specification in the Acceptance Criteria column. Perform an inspection/test of the equipment to assess its safety related conditions. Enter N/A for any parameter or cell that is not used or applicable.			
execution: List any additional safety related conditions or alarms in the Safety Inspection column. List the associated safety requirement/specification in the Acceptance Criteria column. Perform an inspection/test of the equipment to assess its safety related conditions. Enter N/A for any parameter or cell that is not used or applicable.			
Objective evidence: Completed Test Script Data Sheet Photo of the secured glass bottles and/or tanks, if applicable			
Safety Inspection	Acceptance criteria	Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges	None Found	Pass	Rep 20 Jun 2017
Electrical Safety Hi Pot/Ground Continuity	Passed per test specification WAT046538	Pass	Rep 21 Jun 2017
Glass Bottles are secure	Secure	N/A	N/A
Tanks are secure	Secure	N/A	N/A
N/A Rep 27 Jun 2017			
N/A Rep 27 Jun 2017			
N/A Rep 27 Jun 2017			
N/A Rep 27 Jun 2017			
N/A Rep 27 Jun 2017			
N/A Rep 27 Jun 2017			
Comments: H-Pot test performed with Qualtech Guardian6000 Asset #90265 Calibrated 10 Jan 2017			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

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Revision 00
 Document No.: TE0082817-1-IQR
 Attachment: 7.12 Page: 1 of 1



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NVLAP LAB CODE 200972-0

Page 1 of 2

ISSUE DATE: 01/10/2017 Certificate #: 1439002

CUSTOMER / LOCATION WATERS CORPORATION - 5 @ 34 MAPLE STREET DEPT TE MILFORD, MA 01757 DEPT: WP05 PURCHASE ORDER:	EQUIPMENT INFORMATION MANUFACTURER: QUADTECH MODEL NO: GUARDIAN6000 SERIAL NO: 1140657 CONTROL NO: 90265 TYPE: HIPOT, SAFETY ANALYZER
--	---

AS FOUND AS LEFT	IN TOLERANCE IN TOLERANCE	Remarks: ON SITE
-----------------------------------	--	----------------------------

METHOD / ENVIRONMENT PERFORMED: ON SITE METHOD: QUADTECH GUARD 6000	CALIBRATION CALIBRATION DATE: 10/Jan/2017 METROLOGIST: Joe Salindoy Jr CALIBRATION DUE: 31/Jan/2018
--	---

Standards Used To Calibrate Equipment			
I.D.	Template	Type Equipment	Report No.
E231	@ RUBICON 0.1 OHM	STD. RESISTOR	1356768
E2383	@ FLUKE 80K-6-ESSCO	HIGH VOLTAGE PROBE	1337390
E2823	@ FLUKE 85III	DMM	1341760
E3122	@ AGILENT 34401A	DMM	1382262
			06/29/2017
			05/23/2017
			06/01/2017
			08/26/2017

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Iteration 00

The ESSCO Quality System is accredited to ISO 17025:2005

The results above relate only to the items calibrated. Expanded uncertainties were calculated per ISO "Guide to the Expression of Uncertainty Measurement", (GUM) with 95% confidence level and a coverage factor of k=2. This certificate shall not be reproduced, except in full, without written approval of ESSCO. The user should consider the measurement uncertainty when assessing the metrological status of the equipment. This document certifies that the unit conformed to applicable specifications upon successful completion of the calibration. Any number of factors may cause the calibration item to drift out of calibration before the recommended interval has expired. The standards used are traceable to NIST or a National Measurement Institute. This calibration was performed in compliance with the ESSCO Quality System manual, ECL1 Rev 36, dated 16 Dec 2015, ISOMEC 17025 2005, ISO 9001:2008, ANSI/NCCL Z540-1 part 1, ISO 10012:2003, ISO 13485, TS 16949, and when required contractually, 10CFR21 and 10CFR50 App. B.

Kevin R. Pistey

Kevin R. Pistey
Releasing Authority

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government

Internal Use Only: 01/10/2017

DATA EOM

WAT100

169294

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
1	ACV	1000.0	1015.0 985.0	V	996.0	996.0	±3.5 V
2	ACV	3000.0	3035.0 2965.0	V	2985.0	2985.0	±4.6 V
3	ACV	5000.0	5055.0 4945.0	V	5010.0	5010.0	±7.9 V
4	DCV	1000.0	1015.0 985.0	V	996.0	996.0	±0.058 V
5	DCV	3000.0	3035.0 2965.0	V	2994.0	2994.0	± 22.5 V
6	DCV	6000.0	6065.0 5935.0	V	6000.0	6000.0	± 45.0 V
7	ACA	30.00	30.35 29.65	mA	30.01	30.01	±0.065 mA
8	DCA	15.00	15.20 14.80	mA	15.00	15.00	±0.0098 mA
9	IR VOLTAGE	1000.0	1015.0 985.0	V	999.0	999.0	±0.058 V
10	IR RESIST	100.0	105.0 95.0	MOhms	100.2	100.2	±0.058 MOhms
11	IR RESIST	1000.0	1050.0 950.0	MOhms	1000.9	1000.9	±0.58 MOhms
12	GR RESIST	100.0	101.3 98.7	mOhms	100.3	100.3	±0.058 mOhms
13	GR CURRENT	10.00	10.40 9.60	Amp	9.89	9.89	±0.0075 A

End of Data

Note: A = Adjusted F = Failed L = Limited ** = Outside Scope of Accreditation

Iteration 00
 Document No.: TE0012917-1-1QR
 7.13 Page: 2 of 2

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE82817-1	Equipment Name: PCM II Final Test Station		
Installation Site: NPI, Milford, MA			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality.			
Test execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable.			
Objective evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance criteria	Pass/Fail	Initial & Date
UUT Part Number: 186003765 (279001290) UUT Serial Number: F17AP5843M	All required CTQ Specification measurements result in a Pass.	Pass	Exp 20 Jun 2017
Comments: UUT Part # 186003765 contains the PCM II sub-assembly, Part #279001290 as recorded in 735001477 Ver. 05 N/A Exp 27 Jun 2017			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

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Template 730000483 V06

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Iteration 00
 Document No.: TE0082817-1-1QR

Attachment: 7.14 Page: 1 of 1

Waters Corporation

INSTRUMENT FINAL TEST RECORD

Part Number:	186003765	Description:	System Fluidics Organizer
Tested By:	034916ECP	Date:	6/23/2017 3:34:37 PM
Serial Number:	F17APS843M	Control Number:	N/A
Software Revision:	4.00 Build#: 12 (Oct 15 2008)	Factory Order:	4269408

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: *C. E. R.*

Date: 23 Jun/2017

Notes:

N/A ECR 26 Jun 2017

Iteration 00
Document No.: <i>FE0082817-1-1QR</i>
Attachment: <i>7.15</i> Page: <i>1</i> of <i>1</i>

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.

Type	Syllabus ID	Syllabus	Course ID	Course	Attended	Freq	Expires	Score	Status
Requirement	MILTESTENG	Test Engineering	730001834-VER-03	Test Engineering Management Policy	6/9/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730001834-VER-02	New Test Equipment Development Procedure	6/12/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730001835-VER-05	Process Validation Procedure for Milford	6/9/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730001836-VER-01	Sustaining Test Equipment Procedure	6/13/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730001936-VER-03	Test Method Validation Protocol	6/14/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730002232-VER-03	Process Validation Master Plan - Milford	6/14/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730002738-VER-00	New Product Intro Process - Milford (WIDP)	6/14/2017	0			Completed
Requirement	MILTESTENG	Test Engineering	730004135-VER-00	Installation Qualification Protocol	6/13/2017	0			Completed
Requirement	MILMFGOPSALL	All Milford Manufacturing & Support Personnel	EHS0000-VER-02	EHS Policies	6/6/2017	12	6/6/2018		Completed
Requirement	MILMFGOPSALL	All Milford Manufacturing & Support Personnel	LCDHR01-REV-01	Sexual Harassment Policy	6/9/2017	12	6/9/2018		Completed
Requirement	MILMFGOPSALL	All Milford Manufacturing & Support Personnel	QA0002-REV-01	Good Manufacturing Practices	6/12/2017	0			Completed
Requirement	MILMFGOPSALL	All Milford Manufacturing & Support Personnel	QA0008-REV-01	Quality Management Systems	6/13/2017	0			Completed

Iteration 00

Document No.: TE0082817-1-10K

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