

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	Exp 20 Jun 2017
CAL	TE82817 PM Procedure 735002828 Ver 00	Release General	Exp 20 Jun 2017
	N/A		Exp 21 Jun 2017

Comments:

N/A Exp 21 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.: TE0082817-1-10K

Attachment: 7.1 Page: 1 of 1

Title: Installation Qualification Procedure

Document No: 730004135

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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	cep 20 Jun 2017
Relative Humidity	20%-80% non condensing	50%	Pass	cep 20 Jun 2017
Workspace	Adequate free space for testing and service	Adequate space	Pass	cep 20 Jun 2017
Test Station Bench	Large and sturdy enough to hold equipment	Large and sturdy enough	Pass	cep 20 Jun 2017
Electrical Supply	105-129 VAC / 60 Hz	115.72 VAC / 60.01 Hz	Pass	cep 20 Jun 2017
Electrical Outlets	≥ 4	10	Pass	cep 20 Jun 2017
Network Available	≥ 1	1	Pass	cep 20 Jun 2017
N/A cep 27 Jun 2017				

Comments:

Temp and humidity specified in WAT200454 Ver. 00
 ↳ Recorded with Asset# 95648 (Calibrated 15 Nov 2016)
 Electrical Supply specified in WAT200454 Ver. 00
 ↳ Recorded with Asset# 98209 (Calibrated 20 Dec 2016)

Overall Test Conclusion: ☒ Pass ☐ Fail

Copy this Test Script as needed

Iteration 00
 Document No.: TE0082817-1-100

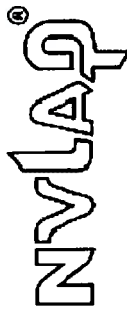
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Attachment: 7.2 Page: 1 of 1



ESSCO CALIBRATION LABORATORY
DIVISION OF WALSH ENGINEERING SERVICES, INC.
CALIBRATION/REPAIR OF ALL TYPES OF ELECTRONIC / MECHANICAL TEST EQUIPMENT
27 INDUSTRIAL AVE, CHELMSFORD, MA 01824-3618
TEL: (800) 325-2201 (978) 250-0880 www.esscolab.com



NVLAP LAB CODE 200972-0

Page 1 of 2

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

CUSTOMER / LOCATION
WATERS CORPORATION - 6 @
34 MAPLE STREET
MILFORD, MA 01757

DEPT: WP72
PURCHASE ORDER: ECL#11/7/2016

EQUIPMENT INFORMATION
MANUFACTURER: EXTECH
MODEL NO: 445703
SERIAL NO: N/A
CONTROL NO: 95648
TYPE: THERMOHYGROMETER

AS FOUND IN TOLERANCE
AS LEFT IN TOLERANCE

Remarks:
IN LAB

METHOD / ENVIRONMENT

PERFORMED: IN LAB
METHOD: ECP NO. 1.3.20 Rev.7 3/17/2016
TEMPERATURE (deg C): 24.1
REL HUMIDITY (%RH): 23.6

CALIBRATION

CALIBRATION DATE: 15/Nov/2016
METROLOGIST: *[Signature]*
CALIBRATION DUE: 30/Nov/2017

Standards Used To Calibrate Equipment
I.D. Template
E2564 THUNDER SCIENTIFIC 2500-LT

Type Equipment
HUMIDITY GENERATOR

Report No. 1377480
Last Cal. Date 08/17/2016
Cal. Due Date 02/26/2017

Document No.: *Iteration 00* TE00828171-10
Attachment: 7.3 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 conforms 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/NCSL 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.

[Signature]
NICHOLAS PAOLETTA
Releasing Authority

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

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.: TE0082817-1-10R

Attachment: 7.3 Page: 2 of 2



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NVLAP LAB CODE 200972-0

ISSUE DATE: 12/20/2016

Certificate #: 1432411

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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	IN TOLERANCE
AS LEFT	IN TOLERANCE

METHOD / ENVIRONMENT

PERFORMED: ON SITE	TEMPERATURE (deg C): 22
METHOD: FLUKE 187/189	REL HUMIDITY (%RH): 19

CALIBRATION

CALIBRATION DATE: 20/Dec/2016	METROLOGIST: <i>B. Bunell</i>
CALIBRATION DUE: 31/Dec/2017	

Remarks:
ON SITE

Standards Used To Calibrate Equipment

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

Document No.: *TE 0082817-1106*
Attachment: 7.4 Page: 1 of 5

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This calibration was performed in compliance with the ESSCO Quality System manual ECL 1 Rev 36, dtd 16 Dec 2015 (ISO/IEC 17025:2005, ISO 9001:2008, ANSI/INCSL 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

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DATA

EOM

WAT100

168494

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

Iteration 00
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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

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Page: 4 of 5
Revision: 00
Date: 12/20/2016

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

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



Iteration 00
Document No.: TE0082817-1-10K
Attachment: 7.5 Page: 1 of 1

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IOQ Test name: Instrumentation Calibration Verification				Test Script No.: IQ-03	
Equipment No./ID: TE82817-1			Equipment Name: PCM II Final Test Station		
Installation Site: NPI, Milford, MA					
Purpose: To verify that all critical instruments are in the calibration system and calibrated or a preventive maintenance has been performed, as appropriate.					
Test execution: List all critical instruments/components and/or sub-systems (System, TUV, Sample Manager, BSM, Column Manager, Test Solutions, Meters, Gauges, Scales, etc.) in the Description column and complete the table below. Verify that all critical instruments have had a preventive maintenance and/or calibration performed, in accordance with the PM and/or Calibration procedures, and have been included in the preventive maintenance/calibration schedule. For test solutions note the expiration date. Enter N/A for any parameter or cell that is not used or applicable.					
Objective evidence: Completed Test Script Data Sheet Copies of calibration and/or maintenance certificates.					
Description	Waters P/N and Asset No.	Serial Number	Last Cal/PM Performed Date	PM Cal/Due / Expiration Date	Initial & Date
PCM II Final Test Station	TE82817-1	N/A	28 Feb 2017	Feb 2018	exp 20 Jun 2017
Comments: N/A exp 22 Jun 2017					
Overall Test Conclusion: ☒ Pass ☐ Fail					

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Iteration 00
 Document No.: TE82817-1-10K
 Attachment: 7.6 Page: 1 of 1

TE82817-1

File Action Edit View Help

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.: TE0082817-1-10R

Attachment: 7.7 Page: 1 of 1

Title: Installation Qualification Procedure

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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	DB 23 Jun 2017
Test Equipment Software ST	Version: 0.0	Version: 0.0	Pass	Exp 23 Jun 2017
PCM II Firmware	Version: 4.00	Version: 4.00	Pass	Exp 26 Jun 2017
	Version:	Version:		
	Version: N/A per	Version:		
	Version:	Version: 27 Jun 2017		
	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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Revision 00

Document No.: TE0082817-1-103

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

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

Title: Installation Qualification Procedure

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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.			
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	exp 20 Jun 2017
Electrical Safety Hi Pot/Ground Continuity	Passed per test specification WAT046538	Pass	exp 21 Jun 2017
Glass Bottles are secure	Secure	N/A	N/A
Tanks are secure	Secure	N/A	N/A
N/A exp 27 Jun 2017			

Comments:

Ht - Pot test performed with Qualtech Guardian 6000 Asset # 90265
 Calibrated 10 Jan 2017

Overall Test Conclusion: ☒ Pass ☐ Fail

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Revision 00

Document No.: TE0082817-1-1A K

Attachment: 7.12 Page: 1 of 1



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

CERTIFICATE OF CALIBRATION

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	
METHOD / ENVIRONMENT			
PERFORMED: ON SITE METHOD: QUADTECH GUARD 6000		TEMPERATURE (deg C): 20 REL HUMIDITY (%RH): 20	
Remarks: ON SITE			
CALIBRATION			
CALIBRATION DATE: 10/Jan/2017 METROLOGIST: <i>Jose Salindoy Jr</i> CALIBRATION DUE: 31/Jan/2018			

I.D.	Template	Type Equipment	Report No.	Last Cal. Date	Cal. Due Date
E231	@ RUBICON 0.1 OHM	STD. RESISTOR	1356768	06/29/2016	06/29/2017
E2383	@ FLUKE 80K-6-ESSCO	HIGH VOLTAGE PROBE	1337390	05/23/2016	05/23/2017
E2823	@ ELUKE 85III	DMM	1341760	06/01/2016	06/01/2017
E3122	@ GILENT 34401A	DMM	1382262	08/26/2016	08/26/2017

Iteration 00
Document No.: TE0082917-10
Attachment: 7.13 Page: 1

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DATA	EOM
or any agency of the Federal Government	

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
Certificate No.: TE0012817-1-10K
7.13 Page: 2 of 2

IOQ 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: F17APS843M	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

Iteration 00

Waters Confidential

Template 730000483 V06

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

Attachment No.: TE0082817-1-10R
V06
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. B. Date: 23 Jun/2017

Notes:

N/A EEP 26 Jun 2017

Iteration 00
Document No.: TE0082817-1-1QR
Attachment: 7.15 Page: 1 of 1

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.

Attachment: 7.16 Page: 1 of 1

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 0.0
Document No.: TE00828 17-1-10K
Attachment: 7.17 **Page:** 1 of 1