

INSTALLATION QUALIFICATION REPORT For the PCM II Final Test Station (TE82817-2)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		13 Nov 2019

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

REVIEWED BY

Name	Role	Signature	Date
Matthew Brule	Senior Test Engineer		
Chan Yee Hwa	Manufacturing Engineer		

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

APPROVED BY

Name	Role	Signature	Date
Tan Kah Chin	Senior Quality Assurance Manager		

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

REVISION HISTORY

VERSION:	00	ORIGINATOR:	Luo HuaZhen	Change ID:	N/A
SUMMARY OF CHANGE: First document for approval, after transfer the tester from Venture Singapore to CEI Singapore					

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of Test Specification and Procedure 735000887 for the TE82817-2, PCM II Final Test Station.

1.1 SYSTEM BACKGROUND

The TE82817-2, PCM II Final Test Station, facilitates the functional test of the following part numbers: 186002449, 800000178, 279001290, 800000224. The system performs testing to ensure the product meets the critical to quality specifications in accordance with TSP 735000887.

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

The PCM II Final Test Station (TE82817-2) is located in the Singapore Contract Manufacturing site CEI Singapore.

2.0 SCOPE

This Installation Report details the Qualification activities undertaken for the TE82817-2, PCM II Final Test Station, based on the requirements of the Installation Qualification Procedure, 730004135 Ver.03, as detailed in TE82817-2-26SEP19-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82817-2, PCM II Final Test Station was tested in accordance with the Installation Qualification Procedure, 730004135 Ver. 03. 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 TE82817-2, 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 TE82817-2, PCM II Final Test Station can be considered fully qualified and fit for intended use.

4.0 DEFINITIONS / ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
ID	Identification
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
PCB	Printed Circuit Board
PCM II	Pump Control Module II
PMP	Pump
ANSI	American National Standards Institute
N/A	Not Applicable

5.0 TRAINING

The operator of the PCM II Final Test Station (TE82817-2) was trained according to the PCM II Final Test Procedure, 735000887, Ver. 06. The executor of this qualification was trained according to the Installation Qualification Procedure 730004135, Ver. 03. Both training records are provided as Attachments 7.16 and 7.17, respectively.

6.0 QUALIFICATION Results

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. 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 Jussume	
B	TSP	735000887	01	PCM II Final Test Procedure	10/20/2004	9111529	RELEASE GENERAL	Mark Jussume	
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 Jussume	
E	TSP	735000887	04	PCM II Final Test Procedure	11/12/2014	9193031	RELEASE GENERAL	Mark Jussume	
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	03/24/2017	9215744	RELEASE GENERAL	Mark Jussume	

6.1.2 The TE82817-2 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	01/20/2013	9176534	RELEASE GENERAL	Mark Jussume	

6.2 Test Script IQ-02: Site Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.2.

6.2.1 The ambient temperature and humidity were measured using a Prostat Psychrometer PHT-771, ID#10169590, 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 117 Multimeter, ID#37781258WS, and was determined to be within specification accordance with ANSI C84.1 – Voltage Tolerance Standard. The calibration record is provided as Attachment 7.4.

6.2.3 The Test Station was confirmed to have more than the four (4) dedicated electrical outlets required.

6.2.4 The space and test bench of the PCM II Final Test Station (TE82817-2) 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. 03. The completed script is provided as Attachment 7.6.

- 6.3.1 The PCM II Final Test Station (TE82817-2) was confirmed to be in the Tooling/Equipment PM Master List with a three (3) month maintenance cycle.
- 6.3.2 The Test Station was confirmed to have had preventative maintenance within this time frame. A copy of the PCM II Final Test Station (TE82817-2) from the Tooling/Equipment PM Master List is provided as Attachment 7.7.
- 6.4 Test Script IQ-04: Test Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 03. 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. A screen capture of the program displays is provided as Attachments 7.9.
 - 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 7.10.
- 6.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.11.
 - 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 7.12.
- 6.6 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.13.
 - 6.6.1 One (1) UUT Part #186002449 (Serial #M18PC2543G) was tested using the PCM II Final Test Station (TE82817-2) program with all tests passing. The final test record is provided as attachment 7.14.
- 6.7 This table provides a summary of each test script as performed according to 730004135 Ver. 03 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, and 7.10	None
IQ-05	Pass	Attachments 7.11 and 7.12	None
IQ-06	Pass	Attachments 7.13 and 7.14	None

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: Prostat Psychrometer PHT-771 (ID#10169590) Calibration Record
- 7.4 Objective Evidence IQ-02: Fluke 117 Multimeter (ID#37781258WS) 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: Tooling/Equipment PM Master List
- 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 Test Equipment Firmware
- 7.11 Completed Test Script IQ-05: General Safety and Alarms
- 7.12 Objective Evidence IQ-05: Hi-Pot Ground Continuity Tester (ID#19032G400225) Calibration Record
- 7.13 Completed Test Script IQ-06: Functional Verification of UUT Part #186002449 (M18PC2543G)
- 7.14 Objective Evidence IQ-06: Instrument Final Test Record for UUT Part #186002449
- 7.15 Completed Operator Training Record 735000887 Ver. 06
- 7.16 Completed Executor Training Record 730004135 Ver. 03

8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution of the Installation Qualification Procedure 730004135 Ver. 03.

9.0 References

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

Document Number	Document title
730004135 Ver. 03	Installation Qualification Procedure
735000887 Ver. 06	PCM II Final Test Procedure
735002828 Ver. 00	TE82817 PM Procedure
WAT200454 Ver. 00	Performance Spec, PCB, PMP Control
WAT046538 Ver. 12	Generic Electrical Safety Test Procedure
361000331 Ver. 00	Pump Control Module II Recreate Procedure v4.00.12
ANSI C84.1	Voltage Tolerance Standard

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 1 of 8

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station	
Installation Site: Waters Singapore Contract Manufacturing, CEI Singapore				
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, then complete the table below. Rows may be added/removed as needed. - All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section.				
Objective Evidence: - Completed IQ-01 Test Script Data Sheet - SAP screenshots of below available document(s)				
Document Type	Title, Doc. #, Version/Revision #		Status in SAP	Initial & Date
TSP	PCM II FINAL TEST PROCEDURE 735000887 REV. G		RELEASE GENERAL	HZ 12Nov2019
Cal	TE82817 PM PROCEDURE 735002828 REV. A		RELEASE GENERAL	HZ 12Nov2019
Comments: N/A HZ 12Nov2019				
Overall Test Conclusion			Document No.: <u>TE82817-2-IQR</u> Iteration No.: <u>00</u> Attachment: <u>7.1</u> Page: <u>1</u> of <u>1</u>	
☒ Pass ☐ Fail				

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 2 of 8

Test Script #	IQ -02	IQ Test Name:	Site Verification		
Equipment #	TE82818-2	Equipment Name:	TCM II Final Test Station		
Installation Site: Waters Singapore Contract Manufacturing, CEI Singapore					
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test Execution: - List additional applicable parameters in the Parameters column. Rows may be added as needed. - Using the applicable equipment documentation, define the specification(s) in the Acceptance Criteria column. - 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. The reason for why the parameter is not used or applicable shall be explained within the corresponding Installation Qualification Report. Objective Evidence: - Completed IQ-02 Test Script Data Sheet - Photo(s) of the work area, as applicable - The source of each Acceptance Criterion shall be referenced in the IQR if stored in SAP. If not in SAP objective evidence specifying the Acceptance Criterion shall be provided in or as an attachment to the IQR. - Copies of calibration certificates for measurement tools, if applicable					
Parameters	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Ambient Temperature	0 °C to 40 °C	23.3°C	Pass	H2 12Nov2019	
Relative Humidity	20 % to 80 %, Non-Condensing	50.1%	Pass	H2 12Nov2019	
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz ±5%	239VAC / 60Hz	Pass	H2 12Nov2019	
Electrical Outlets	Minimum of 4 dedicated outlets	10	Pass	H2 12Nov2019	
Network Available	Minimum of 1 dedicated network	1	Pass	H2 12Nov2019	
Workspace	The system has sufficient room for the test station, UUT and service		Pass	H2 12Nov2019	
Test Station Bench	The Test Station Bench is large and strong enough to support the station		Pass	H2 12Nov2019	
Comments: - Ambient temperature/humidity measured using a Temperature/Humidity Meter, Psychrometer with ID#10169590 - Electrical supply measured using a Multimeter, Fluk 117 with ID# 37781258WS. Note: If the electrical supply range or tolerance is not specified for voltage and/or frequency, a tolerance of ±5% may be used in accordance with ANSI C84.1 – Voltage Tolerance Standard.					
Overall Test Conclusion			Document No.: TE82817-2-IQR		
☒ Pass ☐ Fail			Iteration No.: 00 Attachment: 7.2 Page: 1 of 1		



MICRO PRECISION CALIBRATION PTE LTD
BLOCK 5008 ANG MO KIO AVENUE 5 #07-02/03
TECHPLACE II SINGAPORE 569874
65 67484384



Certificate of Calibration

Date: July 12, 2019

REVIEWED & APPROVED

Cert No. 551220083103774

Customer:

CEI LIMITED

2 ANG MO KIO AVE 12
SINGAPORE 569707

Name / Dept : KEI MUN KUN / EQM

Signature / Date : [Signature] / 22/7/19

Work Order #: SG-11011373

MPC Control #: 10169590

Asset ID: N/A

Gage Type: PSYCHROMETER

Manufacturer: PROSTAT

Model Number: PHT-771

Size: N/A

Temp/RH: 22°C / 52 %

Location: Calibration performed at MPC facility

Serial Number: 10169590

Department: N/A

Performed By: PRAVEEN RAJENDRAN

Received Condition: IN TOLERANCE

Returned Condition: IN TOLERANCE

Cal. Date: July 12, 2019

Cal. Interval: 12 MONTHS

Cal. Due Date: July 12, 2020

Calibration Notes:

Performance Tests Passed. Please refer to the attached calibration data. (1 page)

Standards Used to Calibrate Equipment

I.D.	Description.	Model	Serial	Manufacturer	Cal. Due Date	Traceability #
CC8451	HUMIDITY/TEMPERATURE INDICATOR & PROBE	HMI41 / HMP46	V0330143 / V0920024	VAISALA	Oct 10, 2019	551220081610400

Procedures Used in this Event

Procedure Name	Description
MPC-THD-001	Temperature, Humidity and Dew Point Devices, General, June-1-2017, rev00

Calibrating Technician:

[Signature]
PRAVEEN RAJENDRAN

QC Approval:

[Signature]
JUN CALIMAG

The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k=2$, which for normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined in accordance with EA's Publication and NIST Technical Note 1297, 1994 Edition. Services rendered comply with ISO/IEC 17025:2017, ANSI/NCCL Z540-1-1994, ANSI/NCCL Z540.3-2006, MPC Quality Manual, MPC CSD and with customer purchase order instructions.

Calibration cycles and resulting due dates were submitted/approved by the customer. Any number of factors may cause an instrument to drift out of tolerance before the next scheduled calibration. Recalibration cycles should be based on frequency of use, environmental conditions and customer's established systematic accuracy. The information on this report, pertains only to the instrument identified.

All standards are traceable to SI through the National Institute of Standards and Technology (NIST) and/or recognized national or international standards laboratories. Services rendered include proper manufacturer's service instruction and are warranted for no less than thirty (30) days. This report may not be reproduced in part or in a whole without the prior written approval of the issuing MPC lab.

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.3 Page: 1 of 3



Calibration Report of Prostat PHT-771 Digital Psychrometer

MPC Control #:	10169590	Serial Number:	10169590
Asset ID:	NA	Calibration Date:	July 12, 2019

Temperature Accuracy

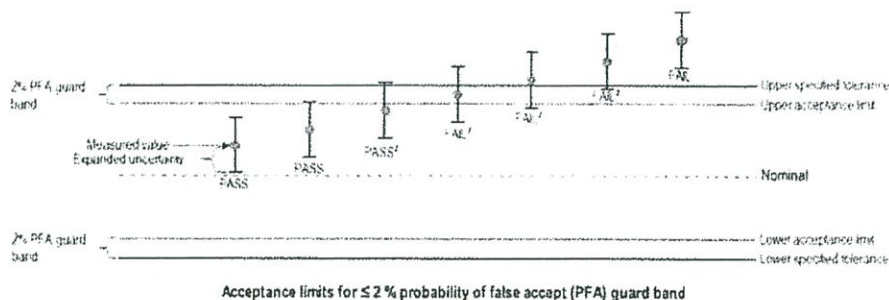
Function Tested	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty ($\pm$)
18 °C @ 45% RH	18.0 °C	17.0 °C	17.7 °C	17.7 °C	19.0 °C	PASS	0.070 °C
23 °C @ 30% RH	23.0 °C	22.0 °C	22.8 °C	22.8 °C	24.0 °C	PASS	0.070 °C
23 °C @ 45% RH	23.0 °C	22.0 °C	22.5 °C	22.5 °C	24.0 °C	PASS	0.070 °C
23 °C @ 60% RH	23.0 °C	22.0 °C	22.3 °C	22.3 °C	24.0 °C	PASS	0.070 °C
30 °C @ 45% RH	30.0 °C	29.0 °C	29.8 °C	29.8 °C	31.0 °C	PASS	0.070 °C

Statements of Pass or Fail Conformance

The uncertainty of measurement has been taken into account when determining compliance with specification, as per IAC-G8/03/2009.
All measurements and test results guard banded to ensure the probability of false-accept does not exceed 2% in compliance with ANSI/NCCL Z540.3-2006.

The status of compliance with the acceptance criteria is reported as:

- PASS - Compliant with specification
- FAIL - Not compliant with specification.
- FAIL² - The measured value is not within the acceptance limits. However, a portion of the expanded uncertainty of measurement at 95% is within the specified tolerance.
- PASS² - The measured value is within acceptance limits. However, a portion of the expanded uncertainty of measurement at 95% exceeds the specified tolerance.



The expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k=2$, which for a normal distribution corresponds to a coverage probability of approximately 95%, unless otherwise stated.
This calibration report complies with ISO/IEC 17025:2017 and ANSI/NCCL Z540.3 Method 6-Guard Bands based on Test Uncertainty Ratio.

- End of Calibration Report -



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[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

CALIBRATION CERTIFICATE

Ref. No. : CEI / 2335

Page : 1 of 6

Customer : CEI Limited
Address : 2 Ang Mo Kio Ave 12
Singapore 569707

REVIEWED & APPROVED

Name / Dept : Lim Hui Hui / E&M

Signature / Date : [Signature] / 17 MAY 2019

Description : Multimeter
Model : 117
Manufacturer : Fluke
Serial No. : 37781258WS

Co-ordinator : Neo Hui Hui
Telephone : 6543 2855
Ext : 207

Date Calibrated : 13 May 2019
Next Due Date : 13 May 2020
Location : Metrology Room

Temperature : $(23 \pm 1) ^\circ\text{C}$
Humidity : $(35 \sim 55) \% \text{rh}$

The above instrument has been tested in general accordance with its manufacturer's published specifications and Performance Test Procedure in Calibration Information, Sep 2006, Rev. 1, 10/08.

The measurement report attached to this certificate indicates all the test results obtained at the time of testing.
The intended use of the instrument shall be ascertained based on the end user's requirement.
Recalibration interval was determined based on end user's requirements.

As Found : ☒ In / ☐ Out Tolerance
As Left : In Tolerance

Adjustment Done : ☐ Yes / ☒ No

The measurement standards are traceable to SI Units through National Metrology Centre (NMC), Singapore; National Institute of Standards and Technology (NIST), USA; National Physical Laboratory (NPL), UK or other recognised National Standard Laboratories.

The Laboratory's Quality System is in accordance with the Quality Standard ISO 9001:2015.

Conformance terms of "In Tolerance" and "Out of Tolerance" used in this certificate are determined by comparison of measured values against warranted specifications and do not take measurement uncertainties into account.

Test Performed By

[Signature]
Liu Yu Tian
Associate Engineer



Approved By

[Signature]
Lim Beng Soon
Senior Manager
13-May-2019

nhh

Note: This Certificate and the attached measurement report shall not be reproduced wholly or in parts without the prior consent of the laboratory

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.4 Page: 1 of 6



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MEASUREMENT REPORT

Page : 2 of 6

Date : 13 May 2019

Reference : CEI / 2335

Description : Multimeter
Model : 117
Manufacturer : Fluke
Serial Number : 37781258WS

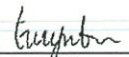
Measuring Instruments used in this performance test :-

Instrument	Serial No. (Cal Report No.)	Eqpt ID	Due Date	Remarks
CALIBRATOR (WITH SCOPE OPT)	9225001 (EL006886)	S0348	03 Aug 2019	

Legend and Explanations for Measurement Report:

- [*] - if shown next to the result recorded, it means the reading is out of the specified limits
[Deviation] - if shown, is computed as [Deviation] = [UUT Reading] - [True Value] (Reference: Int Volcab in Metrology JCGM 200:2008)
[Correction] - if shown, is computed as [Correction] = [True Value] - [UUT Reading].
Correction is used to apply to the UUT reading (add) to give a true reading.

Test Performed By


Liu Yu Tian

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.4 Page: 2 of 6



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MEASUREMENT REPORT

Date : 13 May 2019

Ref. No. : CEI / 2335

Page : 3 of 6

Test	Specified Limits		Results	Comments
Resistance Test				
Range (Ω)	Input (Ω)	Min (Ω)	Max (Ω)	Reading (Ω)
600.0	0.0	0.0	0.2	0.1
600.0	500	495.3	504.7	500.2
6.000 k	5 k	4.954 k	5.046 k	5.000 k
60.00 k	50 k	49.54 k	50.46 k	50.01 k
600.0 k	500 k	495.4 k	504.6 k	500.1 k
6.000 M	5 M	4.954 M	5.046 M	4.998 M
40.00 M	10 M	9.48 M	10.52 M	10.00 M
40.00 M	30 M	28.48 M	31.52 M	29.92 M

Continuity Test

Beeper On at 20 Ω	Pass / Fail	Pass
Beeper Off at 250 Ω	Pass / Fail	Pass

AC Voltage Test

Range (V)	Input (V)	Freq (Hz)	Min (V)	Max (V)	Reading (V)
6.000	5	45	4.947	5.053	4.994
6.000	5	1 k	4.897	5.103	5.005
60.00	50	45	49.47	50.53	49.94
60.00	50	1 k	48.97	51.03	50.00
600.0	600	45	593.7	606.3	599.3
600.0	600	1 k	587.7	612.3	601.8

Frequency Test

Range (V)	Input (V)	Freq (Hz)	Min (Hz)	Max (Hz)	Reading (Hz)
6.000	2	50 k	49.93 k	50.07 k	50.00 k

DC Voltage Test

Range (V)	Input (V)	Min (V)	Max (V)	Reading (V)
6.000	0	-0.002	0.002	0.000
6.000	5	4.973	5.027	4.997
60.00	50	49.73	50.27	49.98
600.0	600	596.8	603.2	599.7
600.0	-600	-603.2	-596.8	-599.7

Test Performed By

Liu Yu Tian

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.4 Page: 3 of 6



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MEASUREMENT REPORT

Date : 13 May 2019

Ref. No. : CEI / 2335

Page : 4 of 6

Test	Specified Limits	Results	Comments
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AC Millivolts Test

Range (V)	Input (V)	Freq (Hz)	Min (V)	Max (V)	Reading (V)
600.0 m	6 m	45	5.6 m	6.4 m	6.2 m
600.0 m	600 m	1 k	587.7 m	612.3 m	600.3 m

DC Millivolts Test

Range (V)	Input (V)	Min (V)	Max (V)	Reading (V)
600.0 m	10 m	9.7 m	10.3 m	10.0 m
600.0 m	600 m	596.8 m	603.2 m	599.8 m

Diode Test

Range (V)	Input (V)	Min (V)	Max (V)	Reading (V)
2.000	1.9	1.881	1.919	1.899

Capacitance Test

Range (F)	Input (F)	Min (F)	Max (F)	Reading (F)
1000 n	Open	0 n	2 n	1 n
9999 μ	900 μ	881 μ	919 μ	900 μ
10.00 μ	9 μ	7.18 μ	10.82 μ	9.00 μ

DC Current Test

Range (A)	Input (A)	Min (A)	Max (A)	Reading (A)
10.00	10	9.87	10.13	10.00

AC Current Test

Range (V)	Input (A)	Freq (Hz)	Min (A)	Max (A)	Reading (A)
6.000	5.0	45	4.922	5.078	4.998

Test Performed By

Liu Yu Tian

Document No.: TE82817-2-IR
Iteration No.: 00
Attachment: 7.4 Page: 4 of 6



Techsystems Services & Integration Asia Pte Ltd

2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913

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[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

Date : 13 May 2019

Ref. No. : CEI / 2335

Page : 5 of 6

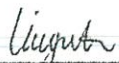
Test	Specified Limits		Results	Comments
Auto-V LoZ Test				
Input (V)	Freq (Hz)	Min (V)	Max (V)	Reading (V)
0.5	45	0.2	0.8	0.5
0.5	0	0.2	0.8	0.5
500	500	489.7	510.3	497.9

Volt Alert Test

At Hi Range, Beeper and Red LED on at 10 V, 60 Hz	Pass / Fail	Pass
At Lo Range, Beeper and Red LED on at 30 V, 60 Hz	Pass / Fail	Pass

Test Completed

Test Performed By


Liu Yu Tian

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.4 Page: 5 of 6



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MEASUREMENT REPORT

Date : 13 May 2019

Ref. No. : CEI / 2335

Page 6 of 6

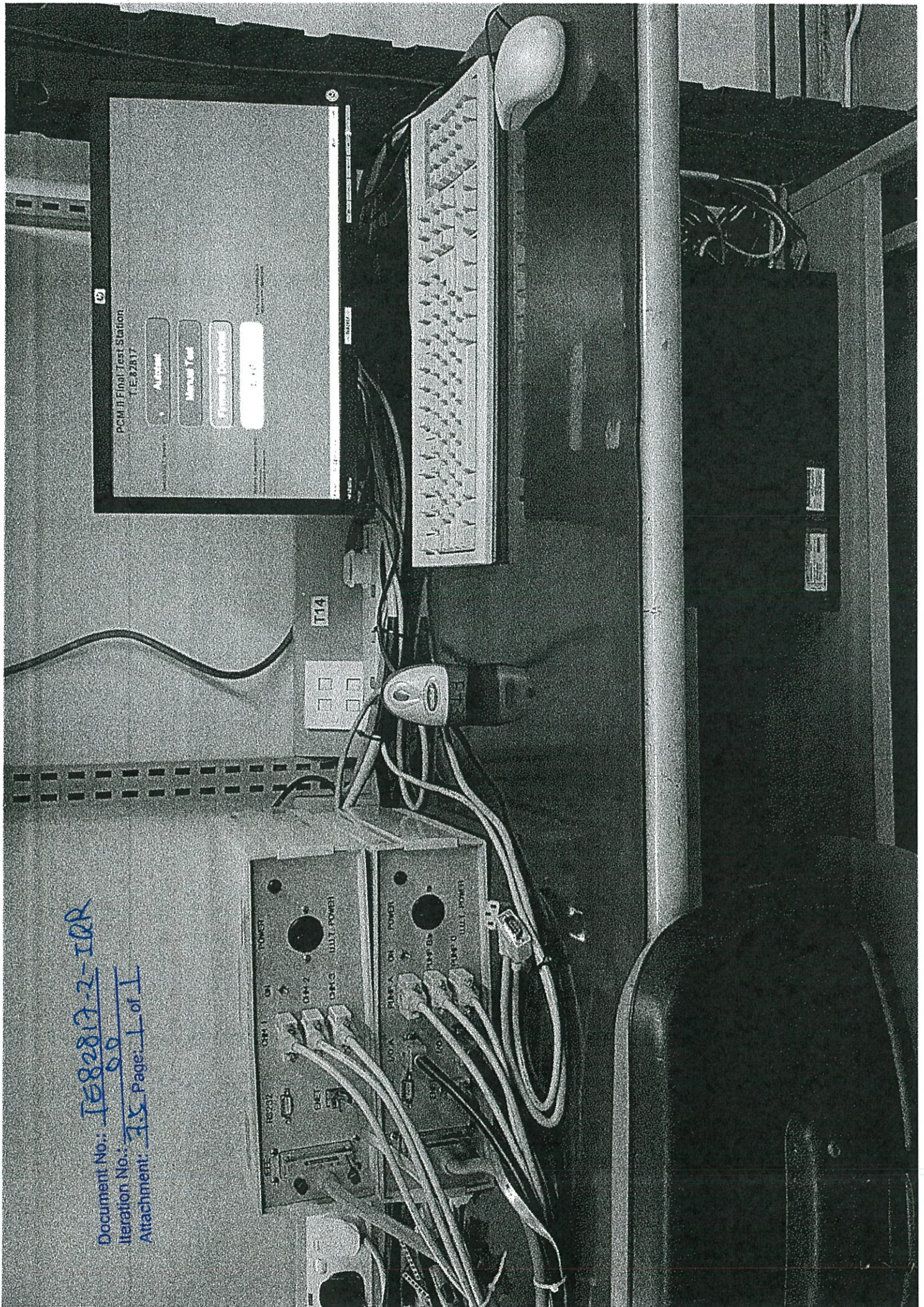
The Expanded Uncertainties of measurement (excluding the uncertainties of the Unit Under Test) for the results given in this report, with a confidence level of approximately 95% at Coverage Factor $k = 2$, are as follows:

Parameters	Range		Uncertainty
Resistance Generation	0 ~ 10.99 Ω		0.014 % + 0.01 Ω
	330 Ω ~ 1.09999 kΩ		0.017 % + 0.07 Ω
	3.3 ~ 10.9999 kΩ		0.010 % + 0.7 Ω
	33 ~ 109.999 kΩ		0.013 % + 7 Ω
	330 kΩ ~ 1.09999 MΩ		0.017 % + 63 Ω
	3.3 ~ 10.9999 MΩ		0.07 % + 635 Ω
	11 ~ 32.9999 MΩ		0.12 % + 635 Ω
AC Voltage Generation	1 ~ 32.999 mV	10 ~ 45 Hz	0.4 % + 23 μV
	0.33 ~ 3.29999 V	45 Hz ~ 10 kHz	0.03 % + 69 μV
	3.3 ~ 32.9999 V	45 Hz ~ 10 kHz	0.05 % + 693 μV
	33 ~ 329.999 V	45 Hz ~ 1 kHz	0.06 % + 8 mV
	330 ~ 1000 V	45 Hz ~ 1 kHz	0.06 % + 92 mV
Frequency Generation	12 ~ 119.99 kHz		29 ppm + 17 mHz
DC Voltage Generation	0 ~ 329.9999 mV		0.0069 % + 3 μV
	0 ~ 3.299999 V		0.0058 % + 6 μV
	0 ~ 32.99999 V		0.0058 % + 50 μV
	30 ~ 329.9999 V		0.0064 % + 500 μV
	100 ~ 1000 V		0.0064 % + 1.5 mV
Capacitance Generation	3.3 ~ 10.999 μF		0.4 % + 11.6 nF
	300 μF ~ 1.1 mF		1.2 % + 346 nF
DC Current Generation	0 ~ 11 A		0.069 % + 381 μA
AC Current Generation	2.2 ~ 11 A	45 ~ 65 Hz	0.06 % + 2309 μA


Liu Yu Tian

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.4 Page: 6 of 6

Document No.: TE82817-2-10R
Iteration No.: 00
Attachment: 3.5 Page: 1 of 1



Installation Qualification Protocol

Document # 730004135

Version # 03

Page 3 of 8

Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station
Installation Site: Waters Singapore Contract Manufacturing, CEI Singapore			
Purpose: To verify that all critical instruments are in the calibration database and that a calibration and/or a preventive maintenance has been performed, as appropriate. Test Execution: - List all critical instruments/components and/or sub-systems that require calibration and/or preventive maintenance in the Description column. Rows may be added as needed. - Verify that all listed critical instruments/components have had a preventive maintenance and/or calibration performed in accordance with the PM and/or Calibration procedure(s) or by an outside source, and are listed within the associated calibration database, then complete the table below. Objective Evidence: - Completed IQ-03 Test Script Data Sheet - Copies of calibration and/or maintenance certificates - Screen captures from the associated Calibration database			
Description	Asset #	Cal/PM Dates	Initial & Date
PCM II Final Test Station	TE82817-2	Last Cal/PM: 06 Nov 2019 Cal/PM Due: 02 Jan 2020	HZ 12 Nov 2019
Comments: N/A JG 12 Nov 2019			
Overall Test Conclusion ☒ Pass ☐ Fail		Document No.: TE82817-2-IQR Iteration No.: 00 Attachment: 7.6 Page: 1 of 1	

CELL LIMITED

6102

Document No.: TE82817-2-102
Iteration No.: 00
Attachment: 7.7 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 4 of 8

Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station		
Installation Site: Waters Singapore Contract Manufacturing, CEI Singapore					
Purpose: To verify that the installed software/firmware is correct per the applicable design and/or operational document(s).					
Test Execution: - List all relevant Equipment software and/or instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed. - List the associated required equipment software and/or critical instrument/internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column. - Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below.					
Objective Evidence: - Completed IQ-04 Test Script Data Sheet - Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report. - Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable					
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Test Equipment Software PCM II	Version: 0.0	Version: 0.0	Pass	H2 12NOV2019	
PCM II Firmware P/N: 361000331	Version: 4.00	Version: 4.00	Pass	H2 12NOV2019	
Comments: Test Equipment Software version specified in 735000887 Rev. G; PCM II Firmware version specified in 361000331 Rev. A					
Overall Test Conclusion ☒ Pass ☐ Fail			Document No.: <u>TE82817-2-IQR</u> Iteration No.: <u>0.8</u> Attachment: <u>7.8</u> Page: <u>1</u> of <u>1</u>		

PCM II Final Test Station

T.E.82817

Switch D.U.T. power on.

Autotest

Manual Test

Firmware Download

Exit

Waters Corporation Inc.
Test Engineering
Test Software revision 0.0

Pump Control Module II
Waters P/N: 186002449

Start   PCM TE82817

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.9 Page: 1 of 1

Step 4 -> Select the file to load

Waters Firmware Update

C:\TE82817\PCMV303.sft

Browse...

The selected file contains firmware for:

Waters **PCM II v4.00**

Checksum: 0x9AF94C9E

< Back Next > Cancel

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.10 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 5 of 8

Test Script #	IQ-05	IQ Test Name:	General Safety and Alarms	
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station	
Installation Site: Waters Singapore Contract Manufacturing, CEI Singapore				
Purpose: To verify that the equipment can operate in a safe manner, within its designated location. Test Execution: - List any additional safety related conditions or alarms in the Safety Inspection column, such as: guarding, interlocks, thermal or mechanical safety, chemical, secured gas tanks, restart or power loss, emergency stop, environmental exhaust, electrical safety, noise, safety labels, etc. Rows may be added as needed. EH&S shall be consulted as necessary. - List the associated safety requirement(s)/specification(s) in the Acceptance Criteria column. - Perform an inspection/test of the equipment to assess its safety related conditions, then complete the table below. Objective Evidence: - Completed IQ-05 Test Script Data Sheet - Photo(s) of the secured glass bottles, tanks, etc., if applicable - The source of any applicable Acceptance Criterion shall be summarized in the IQR if stored in SAP. If the source is not stored in SAP, at a minimum the page specifying the applicable Acceptance Criterion shall be provided as an attachment.				
Safety Inspection	Acceptance Criteria		Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges	None Found (or mitigated appropriately)		Pass	HZ 12 Nov 2019
Glass Bottles	Secure		N/A	N/A
Waste Tanks	Secure and located below the system		N/A	N/A
Emergency Stop	System ceases operation upon depressing the Emergency Stop button		N/A	N/A
Guarding	Shielding in place to prevent hazard during operation		Pass	HZ 12 Nov 2019
Comments: Hi-Pot test performed with Safety Analyzer, chroma 19032 (ID# 190326400225)				
Overall Test Conclusion			Document No.: TE82817-2-IQR	
☒ Pass ☐ Fail			Iteration No.: 00 Attachment: 7.11 Page: 1 of 1	



MICRO PRECISION CALIBRATION PTE LTD
BLOCK 5008 ANG MO KIO AVENUE 5 #07-04
TECHPLACE II SINGAPORE 569874
65 67484384



Certificate of Calibration

REVIEWED & APPROVED

Cert No. 551220082855169

Date: March 11, 2019

Customer:

CEI LIMITED

2 ANG MO KIO AVE 12
SINGAPORE 569707

Name / Dept : Jason Wang / Process

Signature / Date : Jason Wang 14 MAR 2019

Work Order #: SG-11010180

MPC Control #: 19032G400225
Asset ID: NA
Gage Type: ELECTRICAL SAFETY ANALYZER
Manufacturer: CHROMA
Model Number: 19032
Size: N/A
Temp/RH: 23.7°C / 51 %
Location: Calibration performed at Customer's facility

Serial Number: 19032G400225
Department: N/A
Performed By: SENGTHYE CHEW
Received Condition: IN TOLERANCE
Returned Condition: IN TOLERANCE
Cal. Date: March 11, 2019
Cal. Interval: 12 MONTHS
Cal. Due Date: March 11, 2020

Calibration Notes:

Please refer to the attached calibration data. (3 pages).

Standards Used to Calibrate Equipment

I.D.	Description	Model	Serial	Manufacturer	Cal. Due Date	Traceability #
CA8201	225MHZ UNIVERSAL COUNTER	53132A	MY40004745	AGILENT	May 4, 2019	551220081351492
CT2147	SIGNAL GENERATOR	SMA 100A-B103-B22	103536	ROHDE & SCHWARZ	Mar 8, 2020	551220082852034
CA8100	DECADE RESISTANCE BOX	2793	00060U	YOKOGAWA	Jun 1, 2019	551220081403632
CA8198	PRECISION DECADE DC RESISTANCE BOX	SB2015-3	CA8198	CEPREI	Apr 12, 2019	17002776-0001
CA8105	HIGH VOLTAGE DIGITALMETER	149-10A	VM002242	KIKUSUI ELECTRONICS CORP.	Mar 22, 2019	512200813312786
CA8106	CALIBRATOR FOR W.TESTER	TOS1200	VL002591	KIKUSUI ELECTRONICS CORP.	Mar 22, 2019	512200813312795
CH2324	CURRENT SHUNT	34330A	0804	AGILENT	Sep 7, 2019	551220081550844
AP4205	MULTIMETER	3458A	2823A17096	HEWLETT PACKARD	Oct 10, 2019	551220081610396

Calibrating Technician:

SENGTHYE CHEW

QC Approval:

JULES PHILIPPE AGPANGAN

The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k=2$, which for normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined in accordance with EA's Publication and NIST Technical Note 1297, 1994 Edition. Services rendered comply with ISO/IEC 17025:2017, ANSI/NCSL Z540-1-1994, ANSI/NCSL Z540-3-2006, MPC Quality Manual, MPC CSD and with customer purchase order instructions.

Calibration cycles and resulting due dates were submitted/approved by the customer. Any number of factors may cause an instrument to drift out of tolerance before the next scheduled calibration. Recalibration cycles should be based on frequency of use, environmental conditions and customer's established systematic accuracy. The information on this report, pertains only to the instrument identified.

All standards are traceable to SI through the National Institute of Standards and Technology (NIST) and/or recognized national or international standards laboratories. Services rendered include proper manufacturer's service instruction and are warranted for no less than thirty (30) days. This report may not be reproduced in part or in a whole without the prior written approval of the issuing MPC lab.

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 212 Page: 1 of 5



MICRO PRECISION CALIBRATION PTE LTD
BLOCK 5008 ANG MO KIO AVENUE S #07-04
TECHPLACE II SINGAPORE 569874
65 67484384



Certificate of Calibration

Date: March 11, 2019

Cert No. 551220082855169

Procedures Used in this Event

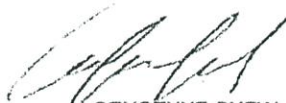
Procedure Name

Description

CHROMA 19032/19032-P

Electrical Safety Analyzer Manual

Calibrating Technician:


SENGTHYE CHEW

QC Approval:


JULES PHILIPPE AGPANGAN

The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k=2$, which for normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined in accordance with EA's Publication and NIST Technical Note 1297, 1994 Edition. Services rendered comply with ISO/IEC 17025:2017, ANSI/NCSL Z540-1:1994, ANSI/NCSL Z540 3-2006, MPC Quality Manual, MPC CSD and with customer purchase order instructions.

Calibration cycles and resulting due dates were submitted/approved by the customer. Any number of factors may cause an instrument to drift out of tolerance before the next scheduled calibration. Recalibration cycles should be based on frequency of use, environmental conditions and customer's established systematic accuracy. The information on this report, pertains only to the instrument identified.

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Document No.: TE82817-2-1QR
Iteration No.: 00
Attachment: 7.12 Page: 2 of 5



CHROMA 19032 ELECTRICAL SAFETY ANALYZER

Procedure: CHROMA 19032/19032-P
 ID Number: 19032G400225
 Asset Number: NA

Order Number: SG-11010180
 Serial Number: 19032G400225
 Calibration Date: March 11, 2019

AC Voltage Accuracy (@60 Hz)

Range	Nominal Value	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty ($\pm$)
0.5 to 5 kV	1.000 kV	0.985 kV	0.998 kV	0.998 kV	1.015 kV	PASS	0.0012 kV
0.5 to 5 kV	2.000 kV	1.975 kV	1.998 kV	1.998 kV	2.025 kV	PASS	0.00060 kV
0.5 to 5 kV	3.000 kV	2.965 kV	2.989 kV	2.989 kV	3.035 kV	PASS	0.00060 kV
0.5 to 5 kV	4.000 kV	3.955 kV	3.985 kV	3.985 kV	4.045 kV	PASS	0.00060 kV
0.5 to 5 kV	5.000 kV	4.945 kV	4.981 kV	4.981 kV	5.055 kV	PASS	0.00060 kV

DC Voltage Accuracy

Range	Nominal Value	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty ($\pm$)
0.5 to 6 kV	1.000 kV	0.985 kV	1.000 kV	1.000 kV	1.015 kV	PASS	0.0025 kV
0.5 to 6 kV	2.000 kV	1.975 kV	1.998 kV	1.998 kV	2.025 kV	PASS	0.0048 kV
0.5 to 6 kV	3.000 kV	2.965 kV	2.994 kV	2.994 kV	3.035 kV	PASS	0.0072 kV
0.5 to 6 kV	4.000 kV	3.955 kV	3.991 kV	3.991 kV	4.045 kV	PASS	0.010 kV
0.5 to 6 kV	5.000 kV	4.945 kV	4.989 kV	4.989 kV	5.055 kV	PASS	0.012 kV
0.5 to 6 kV	6.000 kV	5.935 kV	5.986 kV	5.986 kV	6.065 kV	PASS	0.014 kV

AC Current Accuracy (@60 Hz)

Range	Nominal Value	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty ($\pm$)
1 μ A to 40 mA	0.500 mA	0.490 mA	0.501 mA	0.501 mA	0.510 mA	PASS	0.00059 mA
1 μ A to 40 mA	1.000 mA	0.985 mA	1.001 mA	1.001 mA	1.015 mA	PASS	0.00063 mA
1 μ A to 40 mA	2.000 mA	1.975 mA	1.998 mA	1.998 mA	2.025 mA	PASS	0.00074 mA
1 μ A to 40 mA	5.000 mA	4.945 mA	4.992 mA	4.992 mA	5.055 mA	PASS	0.0017 mA
1 μ A to 40 mA	10.000 mA	9.895 mA	9.989 mA	9.989 mA	10.105 mA	PASS	0.0027 mA
1 μ A to 40 mA	20.00 mA	19.75 mA	19.86 mA	19.86 mA	20.25 mA	PASS	0.0074 mA
1 μ A to 40 mA	35.00 mA	34.60 mA	34.81 mA	34.81 mA	35.40 mA	PASS	0.014 mA



CHROMA 19032 ELECTRICAL SAFETY ANALYZER

Procedure: CHROMA 19032/19032-P
ID Number: 19032G400225
Asset Number: NA

Order Number: SG-11010180
Serial Number: 19032G400225
Calibration Date: March 11, 2019

DC Current Accuracy

Range	Nominal Value	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
0.1 µA to 20 mA	0.200 mA	0.193 mA	0.200 mA	0.200 mA	0.207 mA	PASS	0.00057 mA
0.1 µA to 20 mA	0.500 mA	0.490 mA	0.499 mA	0.499 mA	0.510 mA	PASS	0.00057 mA
0.1 µA to 20 mA	1.000 mA	0.985 mA	0.998 mA	0.998 mA	1.015 mA	PASS	0.00057 mA
0.1 µA to 20 mA	2.000 mA	1.975 mA	1.998 mA	1.998 mA	2.025 mA	PASS	0.00058 mA
0.1 µA to 20 mA	5.000 mA	4.945 mA	4.994 mA	4.994 mA	5.055 mA	PASS	0.00065 mA
0.1 µA to 20 mA	10.000 mA	9.895 mA	9.988 mA	9.988 mA	10.105 mA	PASS	0.00082 mA
0.1 µA to 20 mA	15.00 mA	14.80 mA	14.86 mA	14.86 mA	15.20 mA	PASS	0.0057 mA

Insulation DC Voltage Accuracy

Function Tested	Nominal Value	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
0.500 kV	0.500 kV	0.490 kV	0.501 kV	0.501 kV	0.510 kV	PASS	0.0013 kV
1.000 kV	1.000 kV	0.985 kV	0.998 kV	0.998 kV	1.015 kV	PASS	0.0025 kV

Insulation Resistance Accuracy

Voltage Setting	Nominal Value	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
500 V	1.00 MΩ	0.9 MΩ	1.0 MΩ	1.0 MΩ	1.1 MΩ	PASS	0.0057 MΩ
500 V	10.00 MΩ	9.5 MΩ	9.9 MΩ	9.9 MΩ	10.5 MΩ	PASS	0.0057 MΩ
500 V	100.0 MΩ	95 MΩ	100 MΩ	100 MΩ	105 MΩ	PASS	0.059 MΩ
500 V	1.00 GΩ	0.95 GΩ	0.98 GΩ	0.98 GΩ	1.05 GΩ	PASS	0.59 MΩ
500 V	10.00 GΩ	9.5 GΩ	9.8 GΩ	9.8 GΩ	10.5 GΩ	PASS	0.013 GΩ
1000 V	1.00 MΩ	0.9 MΩ	1.0 MΩ	1.0 MΩ	1.1 MΩ	PASS	0.0057 GΩ
1000 V	10.00 MΩ	9.5 MΩ	10.0 MΩ	10.0 MΩ	10.5 MΩ	PASS	0.0057 MΩ
1000 V	100.0 MΩ	95 MΩ	100 MΩ	100 MΩ	105 MΩ	PASS	0.059 MΩ
1000 V	1.00 GΩ	0.95 GΩ	0.99 GΩ	0.99 GΩ	1.05 GΩ	PASS	0.59 MΩ
1000 V	10.00 GΩ	9.5 GΩ	9.7 GΩ	9.7 GΩ	10.5 GΩ	PASS	0.013 GΩ

Ground Bond AC Current Accuracy

Function Tested	Nominal Value	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
5.000 A	5.000 A	4.947 A	4.998 A	4.998 A	5.053 A	PASS	0.0073 A
10.000 A	10.000 A	9.897 A	10.003 A	10.003 A	10.103 A	PASS	0.014 A
15.00 A	15.00 A	14.82 A	15.05 A	15.05 A	15.18 A	PASS	0.022 A
20.00 A	20.00 A	19.77 A	20.12 A	20.12 A	20.23 A	PASS	0.029 A
25.00 A	25.00 A	24.72 A	25.15 A	25.15 A	25.28 A	PASS	0.036 A
30.00 A	30.00 A	29.67 A	30.19 A	30.19 A	30.33 A	PASS	0.043 A



CHROMA 19032 ELECTRICAL SAFETY ANALYZER

Procedure: CHROMA 19032/19032-P
ID Number: 19032G400225
Asset Number: NA

Order Number: SG-11010180
Serial Number: 19032G400225
Calibration Date: March 11, 2019

Resistance Accuracy

Function Tested	Nominal Value	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty ($\pm$)
@ 25 A	100.0 m Ω	98.7 m Ω	99.8 m Ω	99.8 m Ω	101.3 m Ω	PASS	0.15 m Ω

Timer Accuracy Check

Nominal Value	As Found	As Left	Error	Uncertainty ($\pm$)
2.00 s	1.99 s	1.99 s	-0.50 %	0.14 s
6.00 s	5.98 s	5.98 s	-0.33 %	0.14 s
10.00 s	9.98 s	9.98 s	-0.20 %	0.14 s

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.12 Page: 5 of 5

Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station	
Installation Site: Waters Singapore Contract Manufacturing, CEI Singapore				
Purpose: To verify that the system operates as expected. Test Execution: - Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835. - List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column. - Define the appropriate Acceptance Criteria within the Acceptance Criteria column. - Perform a test of the UUT(s), verify the Acceptance Criteria, then complete the table below. If an associated Test Record is being used as objective evidence the Header/Footer information should be verified for accuracy. Objective Evidence: - Completed IQ-06 Test Script Data Sheet - Copy of the Test Record(s) for the UUT(s), as applicable - The UUT(s) selected for this Test Script and the reasoning for why it/they were selected shall be summarized within the associated Installation Qualification Report. - If this Acceptance Criteria is other than "All required CTQ Specification measurements result in a Pass" then it shall be summarized within the associated VAF, Process Validation Plan, and/or Installation Qualification Report. - For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.				
UUT Part Number/Serial Number		Acceptance Criteria	Pass/Fail	Initial & Date
Part Number: 186002449		All required CTQ Specification measurements result in a Pass	Pass	HZ 12Nov2019
Serial Number: M18PC25436		UUT Firmware Version: 4.00	Pass	HZ 12Nov2019
Comments: N/A JG 12Nov 2019				
Overall Test Conclusion		Document No.: TE82817-2-IQR Iteration No.: 00 Attachment: 7.13 Page: 1 of 1		
☒ Pass ☐ Fail				

Waters Corporation

INSTRUMENT FINAL TEST RECORD

Part Number:	186002449	Description:	Pump Control Module II
Tested By:	jason wang	Date:	11/6/2019 10:58:13 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: *Jason Wang* Date: 06 / Nov / 2019

Notes:

NA

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.

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: File Page: 1 of 1

Installation Qualification Protocol

Version # 03

Page 1 of 1

Appendix A: TRAINING RECORD

Document #	735000887	Document Title	TCM II Final Test Procedure	Version	06
				Revision	G

☒ Read and Understood

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

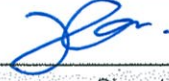
Printed Name	Signature	Initials	Date
Luo HuaZhen			
N/A			
19 SEP 2019			

Document No.: TE82817-2-IQR
Iteration No.: 00
Attachment: 7.15 Page: 1 of 2

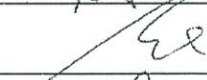
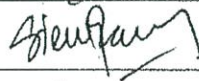
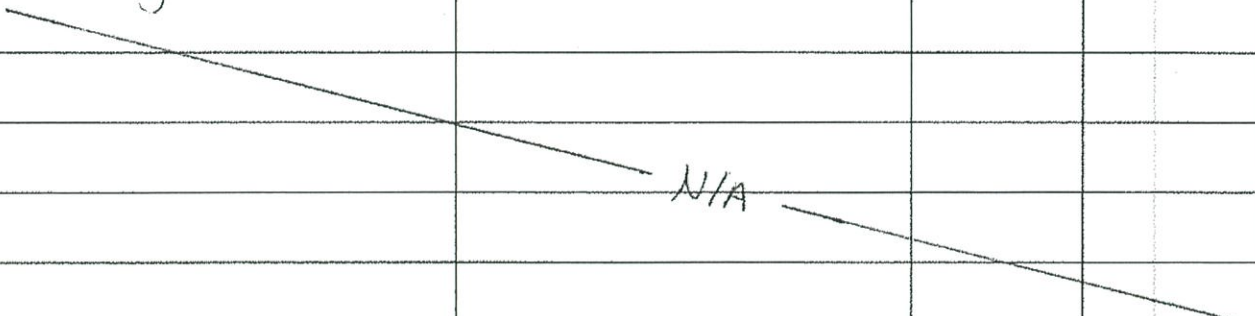
Appendix A: TRAINING RECORD

Document #	735000887	Document Title	PCM II Final Test Procedure	Version	06
				Revision	G

Training Performed By:

Hoa Zhen (waters) / Jason Wang		05 Nov 2019
Printed Name	Signature	Date

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date
Clement Loong		Cloest	05 NOV 2019
Lai Mui Khin		MKLai	05 NOV 2019
Alex EE		Ee T.L.	05 NOV 2019
Sam Yu		H.S.YU	05 NOV 2019
Yong Fook Cheong		YONG FC	05 NOV 2019
Wong Siew Pang		Siew Pang	05 NOV 2019
Anthony Chua		Anthony	05 NOV 2019
			
	N/A		

Print multiple copies of this Training Record Template as needed

Document No.: TE82817-2-IQR
 Iteration No.: 00
 Attachment: 7.15 Page: 2 of 2

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Luo HuaZhen	Employee ID¹	618078
Date of Training	01Mar2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	03

	Senior Test Engineer	19SEP2019
Employee's Signature	Title	Date
	N/A Self Trained	19SEP2019
Trainer's Signature	Title	Date

Document No.: TE82817-2-IQR
 Iteration No.: 00
 Attachment: 7.16 Page: 1 of 1

¹ Without preceding "90"