INSTALLATION QUALIFICATION REPORT
For the TCM II Final Test Station (TE82818-2)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		13Nov2019

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 735000888 for the TE82818-2, TCM II Final Test Station.

1.1 SYSTEM BACKGROUND

The TE82818-2, TCM II Final Test Station, facilitates the functional test of the following part numbers: 186002441, 800000177. The system performs testing to ensure the product meets the critical to quality specifications in accordance with TSP 735000888.

In the final test, the UUT is connected to the test station and the performance of the rear panel I/O, the temperature status and its alarm, unit keypad and LCD display is verified to operate within design specifications. When complete, a hard copy of the final test record is printed

The TCM II Final Test Station (TE82818-2) is located in the Singapore Contract Manufacturing site CEI Singapore.

2.0 SCOPE

This Installation Report details the Qualification activities undertaken for the TE82818-2, TCM II Final Test Station, based on the requirements of the Installation Qualification Procedure, 730004135 Ver.03, as detailed in TE82818-2-26SEP19-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82818-2, TCM 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 TE82818-2, TCM 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 TE82818-2, TCM 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
LCD	Liquid Crystal Display
TCM II	Temperature Control Module II
ANSI	American National Standards Institute
N/A	Not Applicable

5.0 TRAINING

The operator of the TCM II Final Test Station (TE82818-2) was trained according to the TCM II Final Test Procedure, 735000888, Ver. 04. 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 TCM II Final Test Procedure, 735000888, Ver. 04, was confirmed to be in SAP with a status of Release General, as evidenced below.

Document List After Selection *5 Hits*

Choose Save Thumbnails (Images)

RevL	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
A	TSP	735000888	00	000	TCM II Final Test Procedure	RELEASE GENERAL		03.05.2004	19.10.2004	9108646	Mark Jussau...
B	TSP	735000888	01	000	TCM II Final Test Procedure	RELEASE GENERAL		20.10.2004	11.01.2005	9111529	Mark Jussau...
C	TSP	735000888	02	000	TCM II Final Test Procedure	RELEASE GENERAL		12.01.2005	13.11.2014	9113251	Chris Green
D	TSP	735000888	03	000	TCM II Final Test Procedure	RELEASE GENERAL		14.11.2014	23.05.2017	9193028	Mark Jussau...
E	TSP	735000888	04	000	TCM II Final Test Procedure	RELEASE GENERAL		24.05.2017	31.12.9999	9215744	Mark Jussau...

6.1.2 The TE82818-2 PM Procedure, 735004031, Ver. 00, was confirmed to be in SAP with a status of Release General, as evidenced below.

Document List After Selection *1 Hits*

Choose Save Thumbnails (Images)

RevL	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
A	CAL	735004031	00	000	PM Procedure, TE82818	RELEASE GENERAL		27.02.2017	31.12.9999	9213969	Steve Hunt

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, TCM WAT038001, 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 TCM II Final Test Station (TE82818-2) 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 TCM II Final Test Station (TE82818-2) 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 TCM II Final Test Station (TE82818-2) 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 TCM II Final Test Procedure 735000888, Ver. 04 is Test Software 0.0 and was verified to match the version listed in the Test Equipment program displays of the TCM II Test Program. A screen capture of the program displays is provided as Attachments 7.9.

6.4.2 The TCM II Firmware version listed in Production Master TCMII 361000331, Ver. 00 is Firmware v3.02 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 TCM 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 #186002441 (Serial #M18TC2707G) was tested using the TCM II Final Test Station (TE82818-2) 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 TCM 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 #186002441 (M18TC2707G)

7.14 Objective Evidence IQ-06: Instrument Final Test Record for UUT Part #186002441

7.15 Completed Operator Training Record 735000888 Ver. 04

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
735000888 Ver. 04	TCM II Final Test Procedure
735004031 Ver. 00	TE82818 PM Procedure
WAT038001 Ver. 00	Performance Spec, TCM
WAT046538 Ver. 12	Generic Electrical Safety Test Procedure
361000330 Ver. 00	Temperature Control Module II Recreate Procedure v3.02
ANSI C84.1	Voltage Tolerance Standard

Test Script #	IQ-01	**IQ Test Name:**	Associated Documentation Verification
Equipment #	TE82818-2	**Equipment Name:**	TCM 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	TCM II FINAL TEST PROCEDURE 735000888 REV. E	RELEASE GENERAL	HZ 12Nov2019
Cal	TE82818 PM PROCEDURE 735004031 REV. A	RELEASE GENERAL	HZ 12Nov2019

Comments:

N/A 12Nov2019

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: TE82818-2-IQR Iteration No.: 00 Attachment: 7.1 Page: 1 of 1

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	HZ 12Nov2019
Relative Humidity	20 % to 80 %, Non-Condensing	50.1%	Pass	HZ 12Nov2019
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz ±5%	239VAC/60Hz	Pass	HZ 12Nov2019
Electrical Outlets	Minimum of 4 dedicated outlets	10	Pass	HZ 12Nov2019
Network Available	Minimum of 1 dedicated network	1	Pass	HZ 12Nov2019
Workspace	The system has sufficient room for the test station, UUT and service		Pass	HZ 12Nov2019
Test Station Bench	The Test Station Bench is large and strong enough to support the station		Pass	HZ 12Nov2019

Comments:
- Ambient temperature/humidity measured using a Temperature/Humidity Meter, Psychrometer with ID#10169590
- Electrical supply measured using a Multimeter, Fluke 117 with ID # 3778 1258WS

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	
☑ Pass ☐ Fail	Document No.: TE82818-2-IQR Iteration No.: 00 Attachment: 7.2 Page: 1 of 1

MICRO PRECISION

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

ilac-MRA ANAB ACCREDITED
CALIBRATION LABORATORY
AC-1969.15

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 : Lai Mui Khin / EQM
Signature / Date : / 22/7/19

Work Order #: SG-11011373

MPC Control #:	10169590	Serial Number:	10169590
Asset ID:	N/A	Department:	N/A
Gage Type:	PSYCHROMETER	Performed By:	PRAVEEN RAJENDRAN
Manufacturer:	PROSTAT	Received Condition:	IN TOLERANCE
Model Number:	PHT-771	Returned Condition:	IN TOLERANCE
Size:	N/A	Cal. Date:	July 12, 2019
Temp/RH:	22°C / 52 %	Cal. Interval:	12 MONTHS
Location:	Calibration performed at MPC facility	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: PRAVEEN RAJENDRAN

QC Approval: 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/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.

(CERT. Rev 6)

Document No.: TE8288-2-IQR
Iteration No.: 00
Attachment: 7.3 Page: 1 of 2

PRECISION

Calibration Report of Prostat PHT-771 Digital Psychrometer

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

Temperature Accuracy

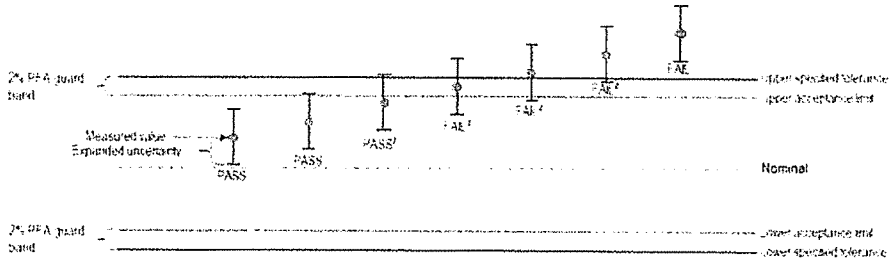
Function Tested	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
18 °C @ 45%RH	18.0 °C	17.0 °C	17.7 °C	17.7 °C	19.0 °C	PASS	0.070 °C
23 °C @ 30%RH	23.0 °C	22.0 °C	22.8 °C	22.8 °C	24.0 °C	PASS	0.070 °C
23 °C @ 45%RH	23.0 °C	22.0 °C	22.5 °C	22.5 °C	24.0 °C	PASS	0.070 °C
23 °C @ 60%RH	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 ILAC-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/NCSL Z540.3-2006.

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

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



Acceptance limits for ≤ 2 % probability of false accept (PFA) guard band

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/NCSL Z540.3 Method 6-Guard Bands based on Test Uncertainty Ratio.

- End of Calibration Report -

Confidential: Controlled Document.
Cannot be reproduced without the approval of the Quality Department

Document No.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7.3 Page: 2 of 2

Techsystems Services & Integration Asia Pte Ltd
2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913
T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com
[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

CALIBRATION CERTIFICATE

Ref. No. : CEI / 2335

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

REVIEWED & APPROVED
Name / Dept : Lai Mei Kin / EGM
Signature / Date : 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 ± 1) °C
Humidity : (35 ~ 55) %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

Liu Yu Tian
Associate Engineer

Techsystems Services & Integration Asia Pte Ltd QC

Approved By

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.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7-4 Page: 1 of 6

Techsystems Services & Integration Asia Pte Ltd
2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913
T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com
[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

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.: TE828/8-2-IQR
Iteration No.: 00
Attachment: 7.4 Page: 2 of 6

Techsystems Services & Integration Asia Pte Ltd
2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913
T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com
[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

Date : 13 May 2019 Ref. No. : CEI / 2335

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.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7.4 Page: 3 of 6

Techsystems Services & Integration Asia Pte Ltd
2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913
T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com
[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

Date : 13 May 2019 Ref. No. : CEI / 2335

Test			Specified Limits		Results	Comments

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.: TE82818-2-IQR
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
T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com
[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

Date : 13 May 2019 Ref. No. : CEI / 2335

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.: TE828/8-2-IQR
Iteration No.: 00
Attachment: 7.4 Page: 5 of 6

Techsystems Services & Integration Asia Pte Ltd
2 Loyang Lane #06-03 | Loyang Industrial Estate | Singapore 508913
T: +65 6543 2855 | F: +65 6543 1329 | W: www.tsiasia.com
[Co Reg No: 199202282R | GST Reg No: M2-0106585-2]

MEASUREMENT REPORT

Date : 13 May 2019 Ref. No. : CEI / 2335

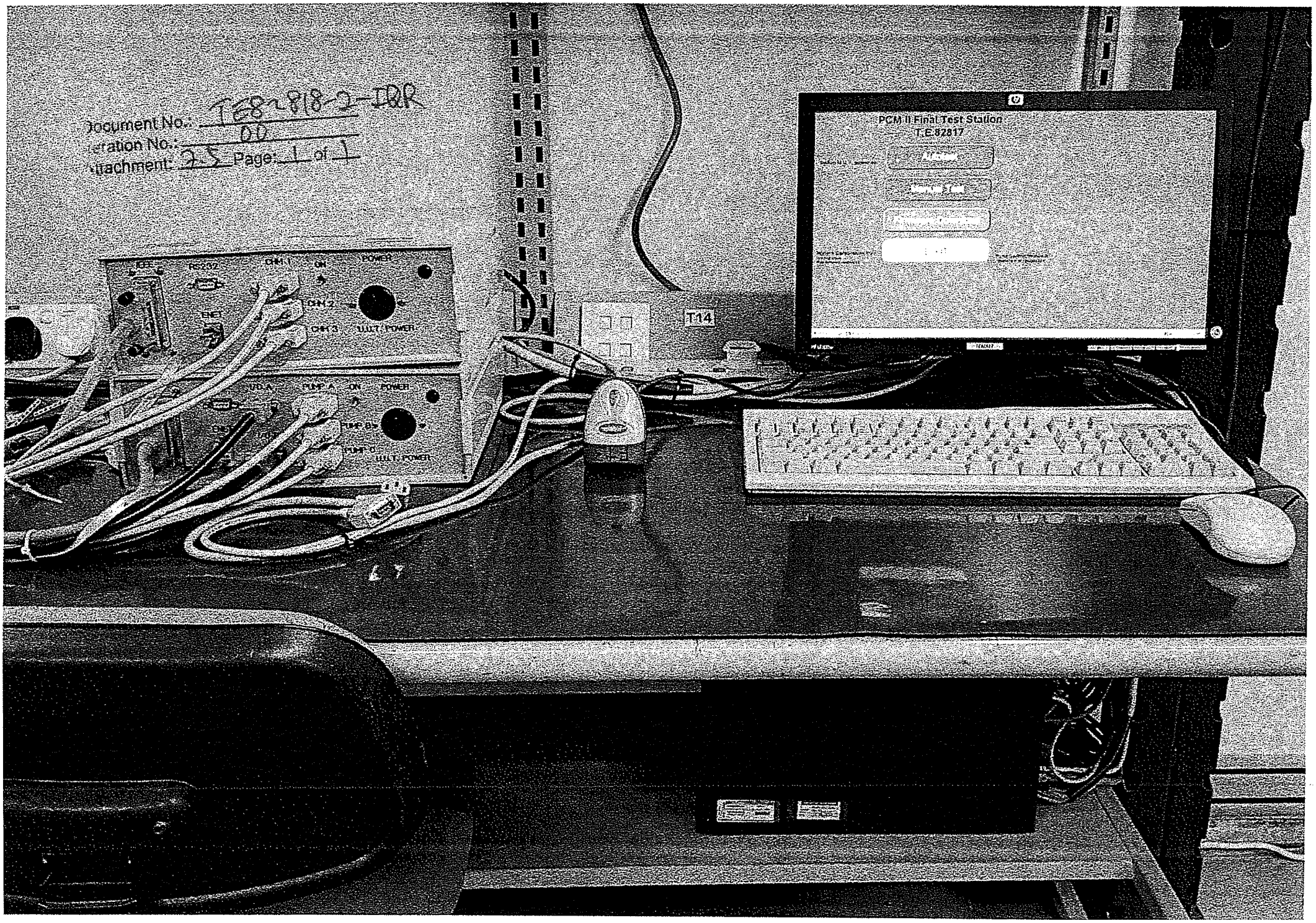
The Expanded Uncertainties of measurement (excluding the uncertainties of the Unit Under Test) for the results given in this report, with a confidence level of approximately 95% at Coverage Factor k = 2), are as follows:

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.: TE8288-2-IQR
Iteration No.: 00
Attachment: 7-4 Page: 6 of 6

Document No.: TE82818-2-I&R
Revision No.: 00
Attachment: 2.5 Page: 1 of 1



Test Script #	IQ-03	**IQ Test Name:**	Instrumentation Calibration Verification
Equipment #	TE82818-2	**Equipment Name:**	TCM 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
TCM II Final Test Station	TE82818-2	Last Cal/PM: 06Nov2019 Cal/PM Due: 02Jan2020	HZ 12Nov2019

Comments:

N/A

12Nov2019

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: TE82818-2-IQR Iteration No.: 00 Attachment: 7.6 Page: 1 of 1

CEI LIMITED
TOOLING/EQUIPMENT PREVENTIVE MAINTENANCE MASTER SCHEDULE

CEI-FRM-MFG-10-R01
Page 1 of 1

Year: 2019

S/N	Location	Tooling/Equipment	Serial number	Frequency	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	WA FINAL TEST	ASO TESTING STATION	TE82865-2	Quarterly			✔			✔			✔			✔
2	WA FINAL TEST	CPSO TESTING STATION	TE82865-5	Quarterly			✔			✔			✔			✔
3	WA FINAL TEST	CPSO TESTING STATION	TE82865-6	Quarterly			✔			✔			✔			✔
4	WA FINAL TEST	PCM II TESTING STATION	TE82817 - 2	Quarterly											✔	
5	WA FINAL TEST	TCM II TESTING STATION	TE82818 - 2	Quarterly											✔	

N/A
12 Nov 2019

Prepared by: Clement Leong Date: 12 Nov 2019

Approved by: Lai Mui Khin Date: 12 Nov 2019

Document No.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7-7 Page: 1 of 1

Test Script #	IQ-04	**IQ Test Name:**	Test Software and Instrument Firmware Version
Equipment #	TE82818-2	**Equipment Name:**	TCM 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 TCM II	Version: 0.0	Version: 0.0	Pass	HZ 12Nov2019
TCM II Firmware P/N: 361000330	Version: 3.02	Version: 3.02	Pass	HZ 12Nov2019

Comments:

Test Equipment Software version specified in 735000888 Rev. E;

TCM II Firmware version specified in 361000330 Rev. A

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: TE82818-2-IQR Iteration No.: 00 Attachment: 7.8 Page: 1 of 1

TCM II Final Test Station
T.E.82818

Select action from menu.
(wait for unit to initialize)

Autotest

Manual Test

Firmware Download

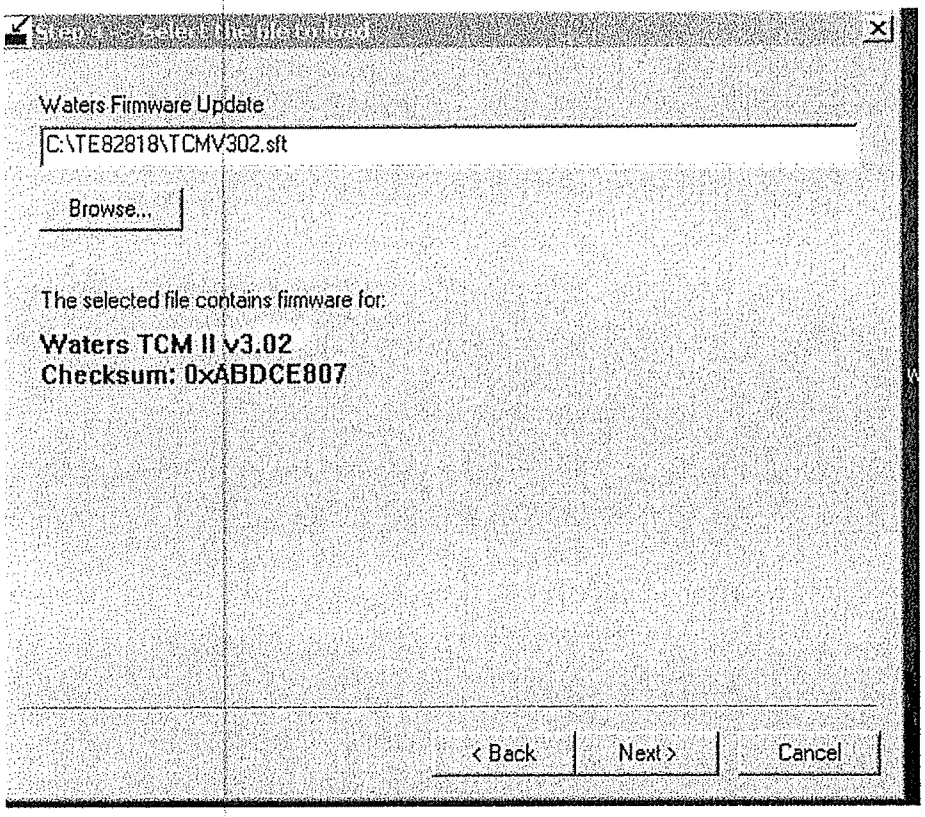
Exit

Waters Corporation Inc
Test Engineering
Test Software revision 0.0

Temp Control Module II

Start | PCM TE82817 | Easy Capture Manager | tester.vi | TE82818

Document No.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7.9 Page: 1 of 1



Document No.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7.10 Page: 1 of 1

Test Script #	IQ-05	**IQ Test Name:**	General Safety and Alarms
Equipment #	TE82818-2	**Equipment Name:**	TCM 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 12Nov2019
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 12Nov2019

Comments:
Hi-Pot test performed with Safety Analyzer, Chroma 19032 with ID# 19032G400225.

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: TE82818-2-IQR Iteration No.: 00 Attachment: 7.11 Page: 1 of 1

MICRO PRECISION

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

ilac-MRA ANAB ACCREDITED CALIBRATION LABORATORY AC-1969.15

Certificate of Calibration

REVIEWED & APPROVED

Name / Dept : Jason Wang / Process

Signature / Date : 14 MAR 2019

Date: March 11, 2019

Cert No. 551220082855169

Customer:
CEI LIMITED
2 ANG MO KIO AVE 12
SINGAPORE 569707

Work Order #: SG-11010180

MPC Control #:	19032G400225	Serial Number:	19032G400225
Asset ID:	NA	Department:	N/A
Gage Type:	ELECTRICAL SAFETY ANALYZER	Performed By:	SENGTHYE CHEW
Manufacturer:	CHROMA	Received Condition:	IN TOLERANCE
Model Number:	19032	Returned Condition:	IN TOLERANCE
Size:	N/A	Cal. Date:	March 11, 2019
Temp/RH:	23.7°C / 51 %	Cal. Interval:	12 MONTHS
Location:	Calibration performed at Customer's facility	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	551220081550644
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 renderedco mply 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.

(CERT, Rev 5)

Document No.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7.12 Page: 1 of 5

MICRO PRECISION

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

ilac-MRA ANAB ACCREDITED CALIBRATION LABORATORY AC-1969.15

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 renderedco mply 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.

(CERT, Rev 5)

Document No.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7.12 Page: 2 of 5

MICRO PRECISION

CHROMA 19032 ELECTRICAL SAFETY ANALYZER

Procedure:	CHROMA 19032/19032-P	Order Number:	SG-11010180
ID Number:	19032G400225	Serial Number:	19032G400225
Asset Number:	NA	Calibration Date:	March 11, 2019

AC Voltage Accuracy (@60 Hz)

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

Document No.: TE-82818-2-IQR
Iteration No.: 00
Attachment: 7.12 Page: 3 of 5

MICRO PRECISION

CHROMA 19032 ELECTRICAL SAFETY ANALYZER

Procedure:	CHROMA 19032/19032-P	Order Number:	SG-11010180
ID Number:	19032G400225	Serial Number:	19032G400225
Asset Number:	NA	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

MICRO PRECISION

CHROMA 19032 ELECTRICAL SAFETY ANALYZER

Procedure:	CHROMA 19032/19032-P	Order Number:	SG-11010180
ID Number:	19032G400225	Serial Number:	19032G400225
Asset Number:	NA	Calibration Date:	March 11, 2019

Resistance Accuracy

Function Tested	Nominal Value	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
@ 25 A	100.0 mΩ	98.7 mΩ	99.8 mΩ	99.8 mΩ	101.3 mΩ	PASS	0.15 mΩ

Timer Accuracy Check

Nominal Value	As Found	As Left	Error	Uncertainty (±)
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.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7.12 Page: 5 of 5

Test Script #	IQ-06	**IQ Test Name:**	Functional Verification
Equipment #	TE82818-2	**Equipment Name:**	TCM 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: 186002441 Serial Number: M18TC27076	All required CTQ Specification measurements result in a Pass	Pass	HZ 12Nov2019
	UUT Firmware Version: 3.02	Pass	HZ 12Nov2019

Comments:

N/A

12Nov2019

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: TE82818-2-IQR Iteration No.: 00 Attachment: 7.13 Page: 1 of 1

Waters Corporation

INSTRUMENT FINAL TEST RECORD

Part Number:	186002441	Description:	Temperature Control Module II
Tested By:	jason wang	Date:	11/6/2019 11:37:54 AM
Serial Number:	M18TC2707G	Control Number:	N/A
Software Revision:	3.02	Factory Order:	1234567

1) Hi - Pot / Ground Continuity	PASS☒	FAIL☐	see note # _____	PASS☐
2) Keypad	PASS☒	FAIL☐	see note # _____	PASS☐
3) LCD display	PASS☒	FAIL☐	see note # _____	PASS☐
4) Temperature Accuracy(101°c - 103°c) Actual °c Chm 1: 102.1 Chm 2: 102.0 Chm 3: 102.0	PASS☒	FAIL☐	see note # _____	PASS☐
5) Temperature Variation(≤.5°c) Actual °c Lowest: 102.0 Highest: 102.1. Variation: 0.11	PASS☒	FAIL☐	see note # _____	PASS☐
6) Heater Verification	PASS☒	FAIL☐	see note # _____	PASS☐
7) Over Temperature Alarm	PASS☒	FAIL☐	see note # _____	PASS☐
8) Under Temperature Alarm	PASS☒	FAIL☐	see note # _____	PASS☐
9) IEEE 488	PASS☒	FAIL☐	see note # _____	PASS☐
10) Set System Defaults	PASS☒	FAIL☐	see note # _____	PASS☐

Instrument Result: PASS☒ FAIL☐ Signed: Jason wang Date: 06 / NOV / 2019.

Notes:

NA.

Document No.: TES28/8-2-FQR
Iteration No.: 00
Attachment: 7.14 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.

Appendix A: TRAINING RECORD

Document #	735000888	**Document Title**	TCM II Final Test Procedure	**Version**	04
				Revision	E

☑ 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

19SEP2019

Document No.: TE82818-2-IQR
Iteration No.: 00
Attachment: 7.15 Page: 1 of 2

Appendix A: TRAINING RECORD

Document #	735000888	Document Title	TCM II Final Test Procedure	Version	04
				Revision	E

Training Performed By:

Printed Name	Signature	Date
Huazhen (Waters) / Jason Wang		05 Nov 2019

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		Clement	05 Nov 2019
lai Mui khin		mklai	05 Nov 2019
Alex EE		Ee T. L.	05 Nov 2019
SAM YU		Sam 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.: TES2818-2-IQR
Iteration No.: 00
Attachment: 7.15 Page: 2 of 2

Training Type:	Read and Understood		
Name:	Luo HuaZhen	**Employee ID**[1]	618078
Date of Training	01Mar2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	03

N/A 19SEP2019

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

Document No.: TES2818-2-IQR
Iteration No.: 00
Attachment: 7.16 Page: 1 of 1

[1] Without preceding "90"