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

PREPARED BY

Name	Role	Signature	Date
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The "Prepared By" signature denotes that this document accurately describes the qualification activities.

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APPROVED BY

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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