INSTALLATION QUALIFICATION REPORT
For the 269X Alliance Heater Cooler Test System

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		22 Mar 2019

REVIEWED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		22 Mar 2019
Tyler Modelski	Test Engineer II		22 Mar 2019

APPROVED BY

Name	Role	Signature	Date
Kah Chin TAN	Senior Quality Assurance Manager		

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

The "Reviewed By" signatures denote agreement with the description of the validation activities.

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

REVISION HISTORY

Version	Author	Summary of change
00	Luo HuaZhen	First document for approval

1.0 Purpose

The 269X Alliance Heater Cooler Test System (TE84018-1) is located at the WPPL Contract Manufacturer Site Flextronics, Singapore. The 269X Alliance Heater Cooler Test System (TE84018-1) is used to perform sub-assembly testing of the part number 289000560.

2.0 Scope of Report

This Installation Report details the details the qualification activities undertaken for the 269X Alliance Heater Cooler Test System (TE84018-1) based on the requirements of the executed Installation Qualification Procedure, 730004135 Version 02.

This Installation Qualification Report defines the documents used to qualify the 269X Alliance Heater Cooler Test System (TE84018-1).

3.0 Summary of Results - Statement of Fitness for Intended Use

The 269X Alliance Heater Cooler Test System (TE84018-1) was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 02. All required Test Scripts were performed, and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the 269X Alliance Heater Cooler Test System (TE84018-1) complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the 269X Alliance Heater Cooler Test System (TE84018-1) can be considered fully qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
%	Percent
#	Number
°C	Degrees Celsius
BOM	Bill of Materials
Cal	Calibration
Cal/PM	Calibration/ Preventive Maintenance
CTQ	Critical to Quality
Doc.	Document
EH&S	Environmental Health and Safety
EQID	Equipment Identification
GDP	Good Documentation Practices
Hz	Hertz
ID	Identification
IQ	Installation Qualification
IQR	Installation Qualification Report
LED	Light Emitting Diode
N/A	Not Applicable
PM	Preventive Maintenance
SAP	Enterprise Resource Planning (ERP) software
TSP	Test and Specification Procedure
UUT	Unit Under Test
VAC	Voltage Alternating Current
VAF	Validation Assessment Form

Term	Explanation
cGMP	Current Good Manufacturing Practice
TMV	Test Method Validation
USL	Upper Specification Limit
LSL	Lower Specification Limit
WPPL	Waters Pacific Private Limited

5.0 Training

The operator of the 269X Alliance Heater Cooler Test System (TE84018-1) was trained according to the Alliance Heater Cooler Test Procedure 735004582, Rev. A, Ver. 00. The executor of this qualification was trained according to the Installation Qualification Procedure 730004135, Ver. 02. Operator and executor training records are provided as Attachment 7.1 and 7.2, respectively.

6.0 Qualification Results

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Procedure 730004135, Ver. 02. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The Alliance Heater Cooler Test Procedure 735004582, Rev. A, Ver. 00 and The Alliance Heater Cooler Cal/PM Procedure 735004597, Rev. A, Ver. 00 were confirmed to be in SAP with a status of Ready. Refer to Attachment 7.4.

6.2 Test Script IQ-02: Site Verification was performed according to Installation Qualification Procedure 730004135, Ver. 02. The completed Test Script Data Sheet is provided as Attachment 7.5.

6.2.1 The ambient temperature and humidity were measured using HOBO Hygrogen Data Logger U14-001, EQID 1494 and were determined to be within specification as defined by the performance specification (WAT270801) of the UUT (refer to SAP). The measurement record and the calibration record of the HOBO Data Logger is provided as Attachment 7.6.

6.2.2 The space and test bench of the 269X Alliance Heater Cooler Test System (TE84018-1) were confirmed to have adequate space for testing and service. The bench was confirmed to be large and strong enough to support all test equipment. The pictures of the work space and test station bench are provided as Attachment 7.7.

6.2.3 The electrical supply was measured using a Fluke 110 Multimeter, EQID-0245, and was determined to be within specification as defined by the AC power requirements listed in the drawing for the power supply WAT270471 (refer to SAP). The measurement record and the calibration record of Fluke 110 Multimeter, EQID-0245 is provided as Attachment 7.8.

6.2.4 The Test Station was confirmed to have minimum of 4 dedicated electrical outlets and 1 dedicated network required. The pictures of electrical outlets and network connection are provided as Attachment 7.8.

6.3 Test Script IQ-03: Instrumentation Calibration Verification was performed according to Installation Qualification Procedure 730004135, Ver. 02. The completed Test Script Data Sheet is provided as Attachment 7.9.

6.3.1 Each component of the 269X Alliance Heater Cooler Test System (TE84018-1) was confirmed to be the Preventive Maintenance Database with a twelve (12) month maintenance cycle. Screen captured from the database is provided as Attachment 7.10.

6.3.2 Note that since this is a newly installed test system, calibration or preventive maintenance has not yet been performed. The calibration/Preventive Maintenance dates listed in the Database reflects date of production.

6.4 Test Script IQ-04: Software and Instrument Firmware Version verification was performed according to Installation Qualification Procedure 730004135, Ver. 02. The completed Test Script Data Sheet is provided as Attachment 7.11.

6.4.1 The Test Equipment Software version listed in Alliance Heater Cooler Test Procedure 735004582, Rev. A, Ver. 00 is Test Software 0.0 and was verified to match the version listed on the test equipment program display. A screen capture of the program display is provided as Attachment 7.12.

6.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Procedure 730004135, Ver. 02. The completed Test Script Data Sheet is provided as Attachment 7.13.

6.5.1 It was confirmed that there were no mechanical safety pinch points or sharp edges.

6.6 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 02. The completed Test Script Data Sheet is provided as Attachment 7.14.

6.5.1 One (1) UUT (P/N: 289000560, S/N: 08K0G045) was tested using the 269X Alliance Heater Cooler Test System (TE84018-1) with all tests passing. A screen capture of passing test record is provided as Attachment 7.15.

6.7 This table provides a summary of each test script as performed according to 730004135, Ver. 02 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	Attachments 7.3 and 7.4	None
IQ-02	Pass	Attachments 7.5, 7.6, 7.7 and 7.8	None
IQ-03	Pass	Attachments 7.9 and 7.10	None
IQ-04	Pass	Attachments 7.11and 7.12	None
IQ-05	Pass	Attachments 7.13	None
IQ-06	Pass	Attachments 7.14 and 7.15	None

7.0 Attachments

7.1 Completed Operator Training Record TSP 735004582, Rev. A, Ver. 00.
7.2 Completed Executor Training Record 730004135, Ver. 02
7.3 Completed Test Script IQ-01: Associated Document Verification
7.4 Objective Evidence IQ-01: Screen Capture of Document Verification in SAP
7.5 Completed Test Script IQ-02: Site Verification
7.6 Objective Evidence IQ-02: The measurement record and the calibration record of the HOBO Data Logger
7.7 Objective Evidence IQ-02: The pictures of the work space and test station bench
7.8 Objective Evidence IQ-02: The measurement record and the calibration record of Fluke 110 Multimeter
7.9 Completed Test Script IQ-03: Instrument Calibration Verification
7.10 Objective Evidence IQ-03: Screen capture of Preventive Maintenance database
7.11 Completed Test Script IQ-04: Software and Instrument Firmware Version verification
7.12 Objective Evidence IQ-04: Screen capture of the test program
7.13 Completed Test Script IQ-05: General Safety and Alarms
7.14 Completed Test Script IQ-06: Functional Verification
7.15 Objective Evidence IQ-06: Screen capture of Passing Test Record for UUT Part #289000560 (S/N: 08K0G045)

8.0 Deviation from Test Method Validation

There were no deviations generated during the execution of the Installation Qualification Procedure 730004135, Ver. 02.

9.0 References

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

Document Number	Document title
730004135	Installation Qualification Procedure
WAT270801	Performance Specification, Heater/Cooler, 2690
WAT270471	The drawing for the power supply
735004582	Alliance Heater Cooler Test Procedure
735004597	Alliance Heater Cooler Cal/PM Procedure

Appendix A: TRAINING RECORD

Document #	735004582	Document Title	Test Specification and Procedure, Alliance Heater Cooler Test	Version	00
				Revision	A

☑ Read and Understood (If self-trained – If not self-trained this section can be deleted)

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
JOEL MAMALATEO OEDLIYO		JMD	04 MAR 19

N/A 04 MAR 2019

Print multiple copies of this Training Record Template as needed

Document No.: TE84018-1-IQR
Iteration No.: 00
Attachment: 7.1 Page: 1 of 1

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	02

N/A 01Mar2019

	Senior Test Engineer	01Mar2019
Employee's Signature	Title	Date
N/A	Self Trained	01Mar2019
Trainer's Signature	Title	Date

Document No.: TE84018-1-IQR
Iteration No.: 00
Attachment: 7.2 Page: 1 of 1

[1] Without preceding "90"

Test Script #	IQ-01	**IQ Test Name:**	Associated Documentation Verification
Equipment #	TE0084018-1	**Equipment Name:**	2690/2790 Alliance Heater Cooler Test System
Installation Site:	Flextronics, 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	Alliance Heater Cooler Test Procedure 735004582 (Version 00, Revision A)	Ready	HZ 04Mar2019
CAL	Alliance Heater Cooler Cal/PM Procedure 735004597 (Version 00, Revision A)	Ready	HZ 04Mar2019

Comments:

N/A
04Mar 2019

Overall Test Conclusion	
☒ Pass ☐ Fail	Document No.: TE84018-1-IQR Iteration No.: 00 Attachment: 7.3 Page: 1 of 1

Objective Evidence: SAP screenshots of below available documents

Alliance Heater Cooler Test Procedure
735004582 (Version 00, Revision A)

Document List After Selection ***1 Hits***

Waters

Choose Save Thumbnails (Images)

RevL	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
	TSP	735004582	00	000	Alliance Heater Cooler Test Procedure	READY					Tyler Model...

Alliance Heater Cooler Cal/PM Procedure

735004597 (Version 00, Revision A)

Document List After Selection ***1 Hits***

Waters

Choose Save Thumbnails (Images)

RevL	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
	CAL	735004597	00	000	Alliance Heater Cooler Cal/PM Procedure	READY					Tyler Model...

Test Script #	IQ -02	**IQ Test Name:**	Site Verification
Equipment #	TE0084018-1	**Equipment Name:**	2690/2790 Alliance Heater Cooler Test System
Installation Site:	Flextronics, Singapore		

Purpose:
To verify the location in which the test equipment is to be installed is suitable for use.

Test Execution:
- List additional applicable environmental/input 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, as appropriate.
- Verify and/or measure the applicable parameters and complete the table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable. 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	4 °C to 40 °C*	20°C	Pass	HZ 04 Mar 2019
Relative Humidity	20 % to 80 %, Non-Condensing*	61%	Pass	HZ 04 Mar 2019
Workspace	Sufficient room for the test station, UUT and service	Sufficient room for the test station, UUT and service	Pass	HZ 04 Mar 2019
Test Station Bench	Large and strong enough to support the station	Large and strong enough to support the station	Pass	HZ 04 Mar 2019
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz	237.6 VAC, 50 HZ	Pass	HZ 04 Mar 2019
Electrical Outlets	Minimum of 3 dedicated outlets	04	Pass	HZ 04 Mar 2019
Network Available	Minimum of 1 dedicated network	01	Pass	HZ 04 Mar 2019

Comments:

*Ambient Temperature / Relative Humidity requirement is based of the performance specification (WAT270801) of the UUT (refer to SAP).
**Electrical Supply requirement is based on the AC power requirements listed in the drawing for the power supply WAT270471 (refer to SAP).

Overall Test Conclusion	
☒ Pass ☐ Fail	Document No.: TE84018-1-IQR Iteration No.: 00 Attachment: 7.5 Page: 1 of 1

Test Script # IQ-02

Ambient Temperature: 20°C

flex

SKW-MFG4018-00

Temperature and Humidity Monitoring Record

Rev: A

Form B

(1) Month / Year : Mar 19

(2) Floor Level : 5th Floor

(3) Area : Production

(4) Equipment Used : HOBO

(5) Serial Number : 10715936

(6) Calibration due date : 13 Jun 19

(7) EQ ID : 1494

(8) Temperature Range : 18°c to 30°c

(9) Humidity Range : 25%RH to 85%RH

Date Check	(10) Time Check	Measurement (24) Temperature (°C)	Measurement (25) Humidity (%RH)	(15) Within Spec.	(16) Out of Control Record (17) Temperature (°C)	(18) Humidity (%RH)	(19) Date Out	(20) Time Out	(21) Name / Signature	(22) NCMR
1	0706	20	61	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah Q	NA
2	0705	21	59	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah Q	NA
3	X	X	X	Yes / No	X	X	X	X	Yep Thim Wah Q	X
4	0725	20	61	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah Q	NA

Relative Humidity : 61

flex

SKW-MFG4018-00

Temperature and Humidity Monitoring Record

Rev: A

Form B

(1) Month / Year : Mar 19

(2) Floor Level : 5th Floor

(3) Area : Production

(4) Equipment Used : HOBO

(5) Serial Number : 10715936

(6) Calibration due date : 13 Jun 19

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Date Check	(10) Time Check	Measurement (24) Temperature (°C)	Measurement (25) Humidity (%RH)	(15) Within Spec.	(16) Out of Control Record (17) Temperature (°C)	(18) Humidity (%RH)	(19) Date Out	(20) Time Out	(21) Name / Signature	(22) NCMR
1	0706	20	61	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah Q	NA
2	0705	21	59	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah Q	NA
3	X	X	X	Yes / No	X	X	X	X	Yep Thim Wah Q	X
4	0725	20	61	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah Q	NA

CALTEK PTE. LTD.

23 Tagore Lane, #04-08/09/10/11 Tagore 23 Warehouse, Singapore 787601
Tel: (65) 64520300 Fax: (65) 64520500
Email: info@caltekgroup.com Website: www.caltekgroup.com

CALIBRATION CERTIFICATE

CERTIFICATE NUMBER :	CTT-111-2497-18	JOB NUMBER	: CTJ18-4213
RECEIVED DATE :	08-Jun-18	ISSUE DATE	: 13-Jun-18

INSTRUMENT	: **DATA LOGGER**	Ambient Temperature	: (23 ± 5) °C
MANUFACTURER	: HOBO	Relative Humidity	: (55 ±10) % r.h.
MODEL NO	: U14-001	Date of Calibration	: 13-Jun-18
PART NO	: -	Recommended Due Date	: 13-Jun-19
SERIAL NO	: 10715936	Instrument Code	: CT7426
		Range	: -
CUSTOMER	: FLEXTRONICS MANUFACTURING (SINGAPORE) PTE LTD.	Asset/Tag/Id/Code	: -/-/1494/-
		Page No	: 1 of 3
		Status	: As Found
		JR No	: JR-10438

The described instrument has been calibrated at Caltek laboratory under the ambient conditions stated above.

This certificate provides traceability of measurement to the International System of Units (SI) and/or to units of measurement realised at the National Metrology Centre (NMC), Singapore or other recognized national metrology institutes.

The calibration method was carried out according to In-house Technical Calibration Procedure CTTM-T17-2007, as guide.

S.No.	REFERENCE INSTRUMENT(S)	SERIAL NO	DUE DATE
1.	Hygrogen	0061445393	22-Aug-18

RESULTS OF CALIBRATION :

1. The expanded uncertainty of measurement associated with the calibration is estimated at a confidence level of approximately 95 % with a coverage factor of k=2.00.
2. The results of calibration are given on the attached calibration data sheet(s).
3. The user should determine the suitability of the instrument for its intended use.
4. No Adjustments done.

Calibrated by :		**Approved by :**	
Kyaw Zin Thant		Anoop Ummappilly	
EMP ID : 1068		EMP ID : 1039	

This certificate may not be reproduced other than in full, except with the prior written approval of the issuing Laboratory.

REVIEWED & ACCEPTED
SIGN: CHANG MEI LAN
DATE: 25 JUN 18
REMARKS: EQID 1494
25 Jun 18
BENNETT CHEONG CHUNHWIN

Document No.: TE84018-1-IQR
Iteration No.: 00
Attachment: 7.6 Page: 2 of 4

CALTEK PTE. LTD.

23 Tagore Lane, #04-08/09/10/11 Tagore 23 Warehouse, Singapore 787601
Tel: (65) 64520300 Fax: (65) 64520500
Email: info@caltekgroup.com Website: www.caltekgroup.com

CALIBRATION CERTIFICATE

CERTIFICATE NUMBER :	CTT-111-2497-18	JOB NUMBER	: CTJ18-4213
ISSUE DATE :	13-Jun-18	PAGE NUMBER	: 2 of 3

Calibration Results:RELATIVE HUMIDITY MEASUREMENT @ FIXED TEMPERATURE OF 23°C

Mean Reference Reading	Mean Instrument Reading - Before Adjustment	Error	Expanded Uncertainty
%rh	%rh	%rh	%rh
23.0	24	1.0	2
40.0	41	1.0	2
60.0	61	1.0	2
80.0	79	-1.0	2
86.0	85	-1.0	2

Calibrated by :		Approved by :	
Kyaw Zin Thant		Anoop Ummappilly	
EMP ID : 1068		EMP ID : 1039	

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Document No.: TE84018-1-IQR
Iteration No.: 00
Attachment: 7.6 Page: 3 of 4

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23 Tagore Lane, #04-08/09/10/11 Tagore 23 Warehouse, Singapore 787601
Tel: (65) 64520300 Fax: (65) 64520500
Email: info@caltekgroup.com Website: www.caltekgroup.com

CALIBRATION CERTIFICATE

CERTIFICATE NUMBER :	CTT-111-2497-18	JOB NUMBER	: CTJ18-4213
ISSUE DATE :	13-Jun-18	PAGE NUMBER	: 3 of 3

Calibration Results:TEMPERATURE MEASUREMENT @ NOMINAL RELATIVE HUMIDITY OF 50%r.h.

Mean Reference Reading	Mean Instrument Reading - Before Adjustment	Error	Expanded Uncertainty
°C	°C	°C	°C
16.00	16.1	0.10	0.4
18.00	18.2	0.20	0.4
22.00	22.2	0.20	0.4
27.00	27.1	0.10	0.4
30.00	29.9	-0.10	0.4

Calibrated by :		Approved by :	
Kyaw Zin Thant		Anoop Ummappilly	
EMP ID : 1068		EMP ID : 1039	

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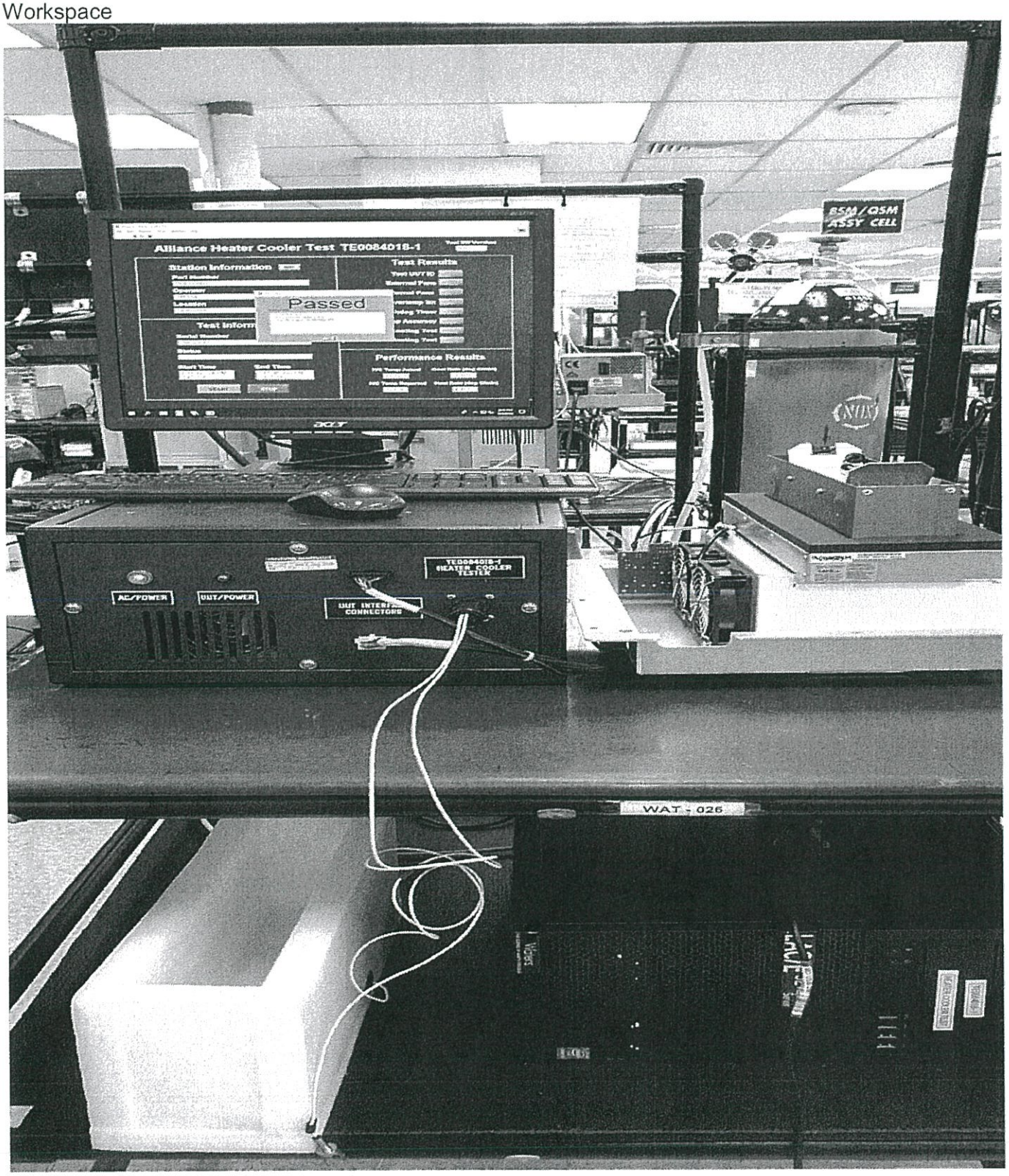
Test Script # IQ-02

Workspace



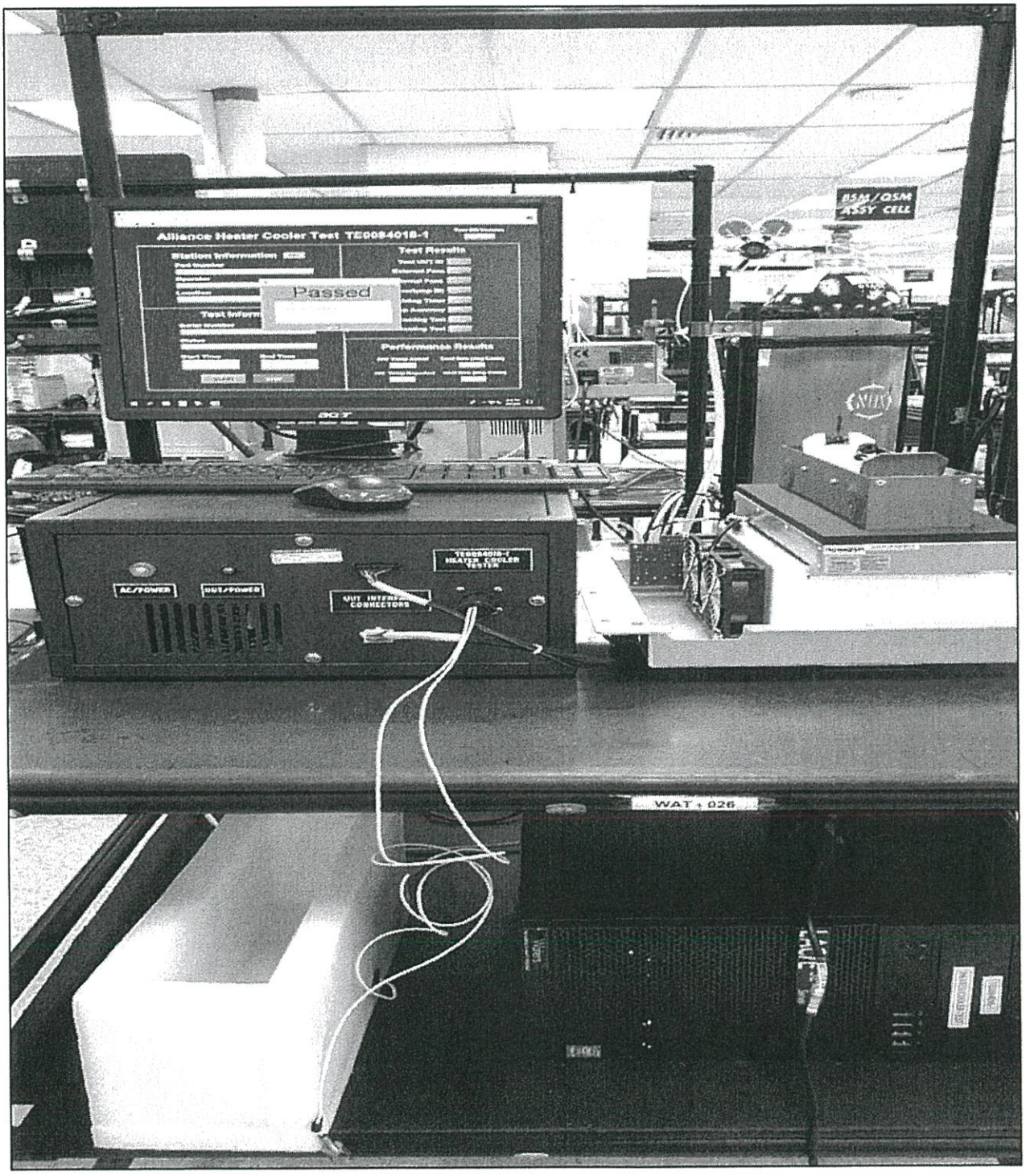
Document No.: TE84018-1-IQR

Iteration No.: 00

Attachment: I-7 Page: 1 of 2

Test Script # IQ-02

Test Station Bench

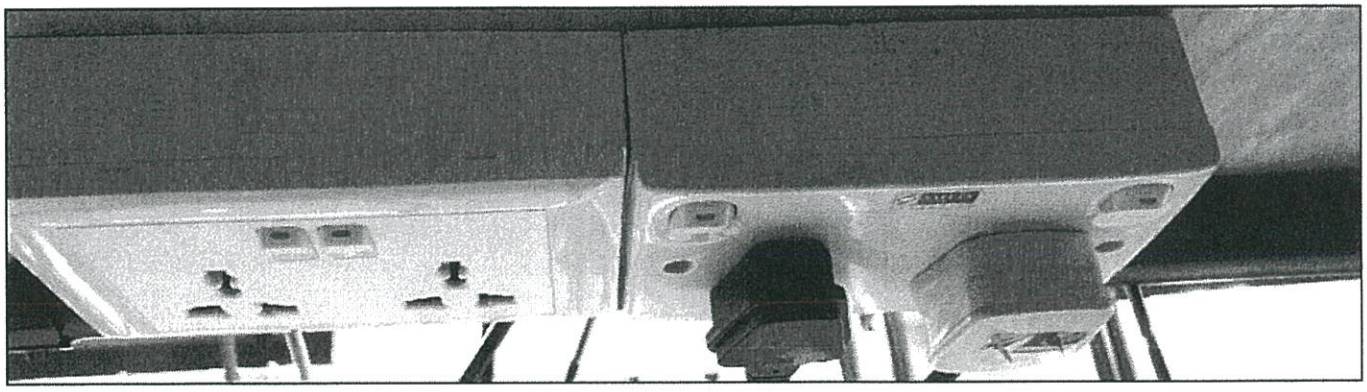


Document No.: TE84018-1-IQR
Iteration No.: 00
Attachment: F.7 Page: 2 of 2

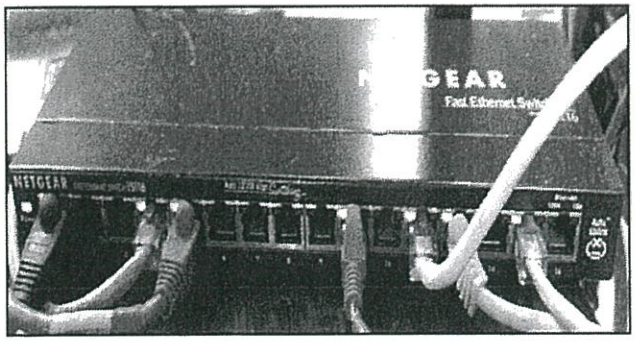
Test Script # IQ-02

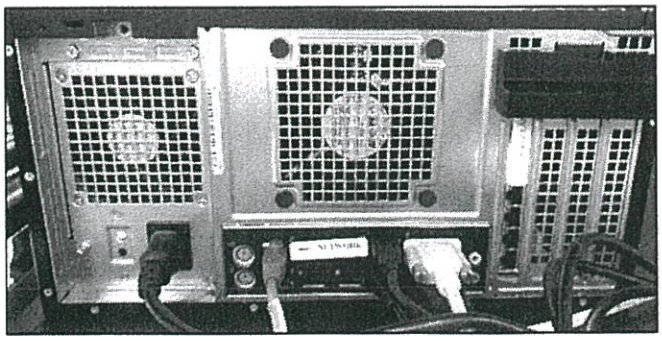
Electrical Supply: 237.6 VAC , 50 Hz

Electrical Outlets



Network Available: Test Station has been verified with dedicated network (Green Ethernet to station CPU)





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. : FMS / 1942

Customer : Flextronics Manufacturing (Singapore) Pte Ltd
Address : 1 Kallang Place
Singapore 339211

REVIEWED & ACCEPTED
SIGN: CHANG MEI LAN
DATE: 07 JAN 19
REMARKS: EQID 0245
JOEL MAM AZAIED
DEDUYD 07 JAN 19

Equipment ID : 0245
Description : Multimeter
Model : 110
Manufacturer : Fluke
Serial No. : 85730619

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

Date Calibrated : 02 Jan 2019
Next Due Date : 02 Jan 2020
Location : Electrical Laboratory

Temperature : (23 ± 3) °C
Humidity : (35 ~ 65) %rh

The above instrument has been tested in general accordance with its manufacturer's published specifications and Performance Test Procedure in Calibration Information PN1608592.

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 Adjustment Done : [ ] Yes / [✓] No
As Left : In Tolerance

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

Muhammad Azuan Bin Ali
Engineer

Approved By

Lim Beng Soon
Senior Manager
02-Jan-2019

Document No.: TE84018-1-IQR
Iteration No.: 00
Attachment: 7.8 Page: 2 of 6

Note This Certificate and the attached measurement report shall not be reproduced wholly or in part without the prior consent of the Management.

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 : 02 Jan 2019

Reference : FMS / 1942

Description : Multimeter
Model : 110
Manufacturer : Fluke
Serial Number : 85730619

Measuring Instruments used in this performance test :-

Instrument	Serial No. (Cal Report No.)	Eqpt ID	Due Date	Remarks
MULTI-PRODUCT CALIBRATOR	6775016 (EL006584)	S0269	26 Apr 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

Muhammad Azuan Bin Ali

Document No.: TE84018-1-IQR
Iteration No.: 00
Attachment: 7.8 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 : 02 Jan 2019 Ref. No. : FMS / 1942

Test			Specified Limits		Results	Comments

AC Voltage Test

Range (V)	Freq (Hz)	Input (V)	Min (V)	Max (V)	Reading (V)
6	50	300 m	0.294	0.306	0.300
6	500	300 m	0.294	0.306	0.301
6	50	5	4.947	5.053	5.004
6	500	5	4.947	5.053	5.003
60	500	50	49.47	50.53	50.27
600	500	600	593.7	606.3	602.4

Frequency Test

Voltage : 5 V

Range (kHz)	Input (kHz)	Min (kHz)	Max (kHz)	Reading (kHz)
50	50	49.93	50.07	49.98

DC Voltage Test

Range (V)	Input (V)	Min (V)	Max (V)	Reading (V)
6	0	-0.002	0.002	0.000
6	5	4.963	5.037	5.001
60	-50	-50.37	-49.63	-50.05
600	600	595.6	604.4	600.5

Continuity Test

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

Resistance Test

Range (Ω)	Input (Ω)	Min (Ω)	Max (Ω)	Reading (Ω)
600	0	-0.2	0.2	0.1
600	500	495.3	504.7	500.2
6 k	5 k	4.954 k	5.046 k	5.000 k
60 k	50 k	49.54 k	50.46 k	49.97 k
600 k	500 k	495.4 k	504.6 k	500.2 k
6 M	5 M	4.954 M	5.046 M	4.993 M
40 M	30 M	29.52 M	30.48 M	29.79 M

Test Performed By

Muhammad Azuan Bin Ali

Document No.: TE 84018-1-IQR
Iteration No.: 00
Attachment: 7.8 Page: 4 of 6

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MEASUREMENT REPORT

Date : 02 Jan 2019 Ref. No. : FMS / 1942

Test		Specified Limits		Results	Comments
Diode Test					
Range (V)	Input (V)	Min (V)	Max (V)	Reading (V)	
2.2	2	1.980	2.020	2.001	
Capacitance Test					
Range (nF)	Input (nF)	Min (nF)	Max (nF)	Reading (nF)	
1000	800	783	817	800	

****
Test Completed

Test Performed By

Muhammad Azuan Bin Ali

Document No.: TE84018-1-IQR
Iteration No.: 00
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MEASUREMENT REPORT

Date : 02 Jan 2019 Ref. No. : FMS / 1942

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
AC Voltage Generation	33 ~ 329.999 mV	45 Hz ~ 10 kHz	0.0058 % + 23 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	1.2 ~ 11.999 kHz		29 ppm + 1 mHz
DC Voltage Generation	0 ~ 32.99999 V		0.0058 % + 50 µV
	30 ~ 329.9999 V		0.0064 % + 500 µV
	100 ~ 1000 V		0.0064 % + 1.5 mV
Resistance Generation	330 ohm ~ 1.09999 kΩ		0.17 % + 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
Capacitance Generation	0.33 ~ 1.0999 µF		0.29 % + 1.2 nF

Muhammad Azuan Bin Ali

Document No.: TE84018-1-IQR
Iteration No.: 00
Attachment: 7.8 Page: 6 of 6

Test Script #	IQ-03	**IQ Test Name:**	Instrumentation Calibration Verification
Equipment #	TE0084018-1	**Equipment Name:**	2690/2790 Alliance Heater Cooler Test System
Installation Site:	Flextronics, 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
TE0084018 Test Box	TE0084018-1	Last Cal/PM: 25 Feb 2019 Cal/PM Due: 25 Feb 2020	HZ 04 Mar 2019

Comments:

N/A

04 Mar 2019

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: TE84018-1-IQR Iteration No.: 00 Attachment: 7.9 Page: 1 of 1

flex.

PREVENTIVE MAINTENANCE MASTER LIST

MONTH / YEAR: FEBRUARY 2019

[1] S/No	[2] WORK ORDER ID	[3] EQUIPMENT ID	[4] DESCRIPTION	[5] EQUIPMENT S/N. (IF ANY)	[6] CUSTOMER EQUIPMENT ID (IF ANY)	[7] EQUIPMENT OWNER	[8] DEPARTMENT	[9] FLOOR	[10] LOCATION	[11] PRODUCT	[12] PM PROCEDURE	[13] INITIAL DATE	[14] PM FREQUENCY									[15] REMARK
													DAILY (Y/N)	WEEKLY (Y/N)	BIWEEKLY (Y/N)	MONTHLY (Y/N)	BIMONTHLY (Y/N)	QUARTERLY (Y/N)	HALF YEARLY (Y/N)	YEARLY (Y/N)	OTHERS	
189	WO 04355	PM 03106	Printer (LaserJet P3005n)	JPKGJ01942	NA	Joel Mamalateo Deduyo	Engineering	5th	Production (Pump Series)	Waters	SKW-RW-SKR00035	15 Aug 18	N	N	N	N	N	N	N	Y	NA	NA
190	WO 04601	PM 03250	Printer (LaserJet Pro M402dn)	PHCNH24481	NA	Joel Mamalateo Deduyo	Engineering	5th	Production (Alliance)	Waters	SKW-RW-SKR00035	13 Dec 18	N	N	N	N	N	N	N	Y	NA	NA
191	WO 04635	PM 03268	Autoloader-3 CPU	8189MU5 KLTL939	186002364	Joel Mamalateo Deduyo	Engineering	5th	Production Floor	Waters	SKW-RW-SKR00035	22 Jan 19	N	N	N	N	N	N	N	Y	NA	NA
192	WO 04677	PM 03300	Heater Cooler Tester	L181.32381W	TE0084018-1	Joel Mamalateo Deduyo	Engineering	5th	Production (Alliance)	Waters	WAT-RW-SKI04210	25 Feb 19	N	N	N	N	N	N	N	Y	NA	NA
			End of Data																			

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Iteration No.: 00
Attachment: 7.10 Page: 1 of 1

Test Script #	IQ-04	**IQ Test Name:**	Test Software and Instrument Firmware Version
Equipment #	TE0084018-1	**Equipment Name:**	2690/2790 Alliance Heater Cooler Test System
Installation Site:	Flextronics, 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
Equipment Test Software	Version: 0.0	Version: 0.0	Pass	HZ 04Mar2019

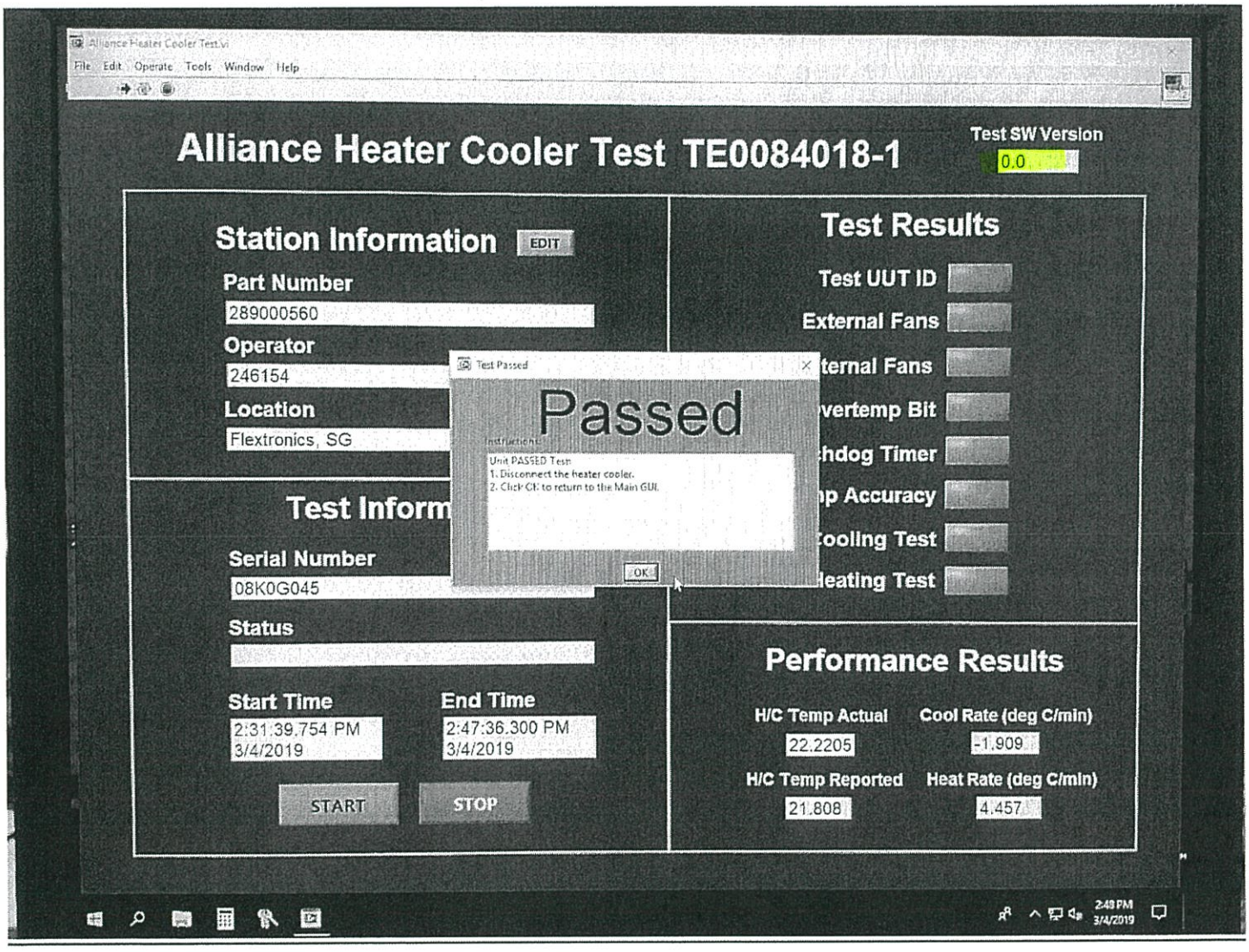
Comments:

N/A JG 04 Mar 2019

Overall Test Conclusion	
☒ Pass ☐ Fail	Document No.: TE84018-1-IQR Iteration No.: 00 Attachment: 7.11 Page: 1 of 1

Test Script # IQ-04

Equipment Test Software : Version 0.0



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Test Script # IQ-05	**IQ Test Name:** General Safety and Alarms
Equipment # TE0084018-1	**Equipment Name:** 2690/2790 Alliance Heater Cooler Test System
Installation Site: Flextronics, 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 04Mar2019

Comments:

N/A JB 04Mar2019

Overall Test Conclusion	
☒ Pass ☐ Fail	Document No.: TE84018-1-IQR Iteration No.: 00 Attachment: 7.13 Page: 1 of 1

Test Script # IQ-06	**IQ Test Name:** Functional Verification
Equipment # TE0084018-1	**Equipment Name:** 2690/2790 Alliance Heater Cooler Test System
Installation Site: Flextronics, 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: 289000560 Serial Number: 08K06045	All required CTQ Specification measurements result in a Pass	Pass	HZ 04Mar2019

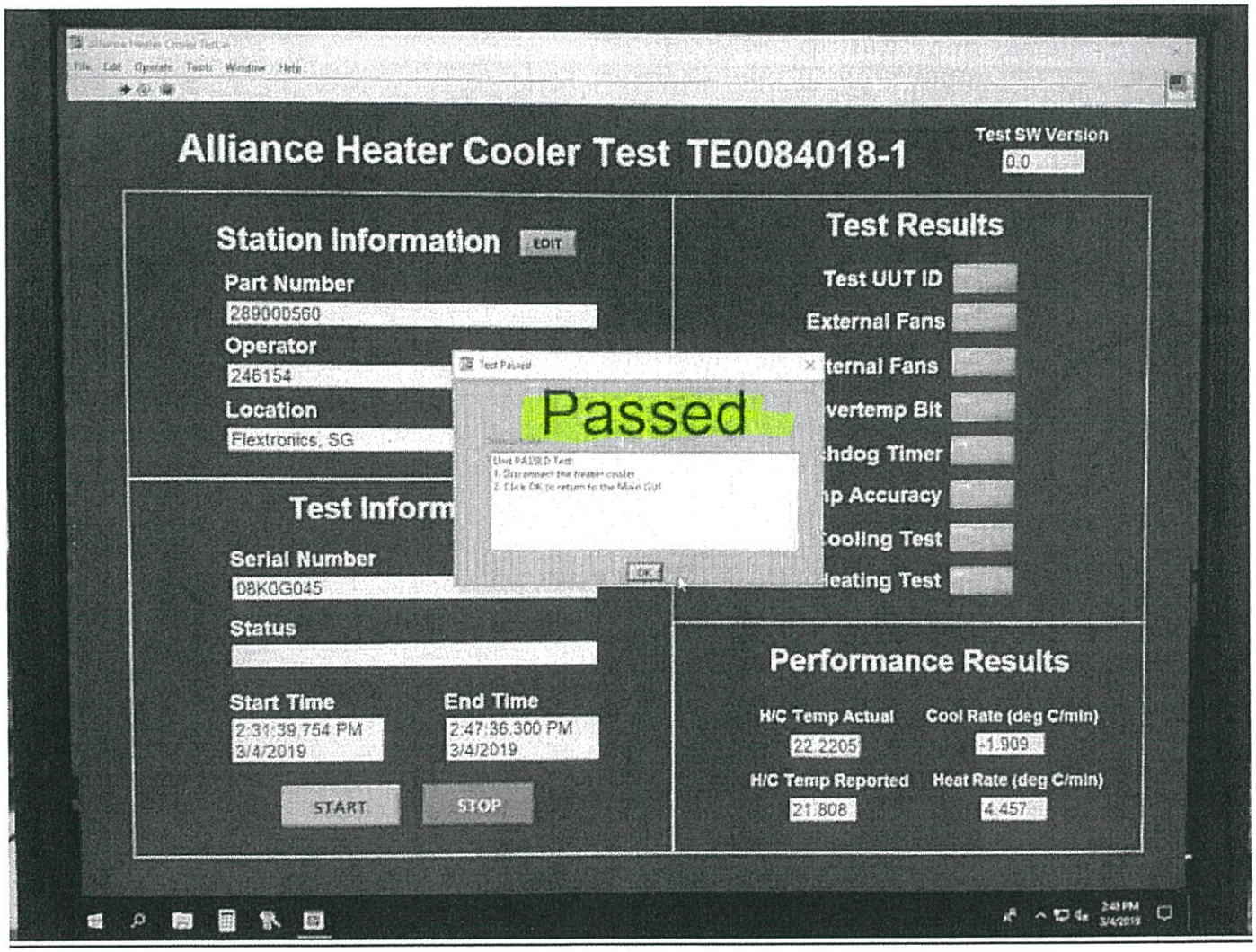
Comments:

N/A JG 04Mar2019

Overall Test Conclusion	
☒ Pass ☐ Fail	Document No.: TE8401 8-1-IQR Iteration No.: 00 Attachment: 7.14 Page: 1 of 1

Test Script # IQ-06

Part Number: 289000560
Serial Number: 08K0G045



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