

Title: individual Training Form

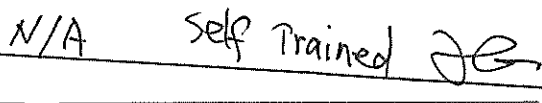
Document No: 730002657

Version No: 00

Page 1 of 1

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

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	02

	Senior Test Engineer	01 Mar 2019
Employee's Signature	Title	Date
	N/A Self Trained	01 Mar 2019
Trainer's Signature	Title	Date

¹ Without preceding "90"



WORK INSTRUCTION

Title: *Installation Qualification Protocol*

Version # 02

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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.

[illegible]

Print multiple copies of this Training Record Template as needed

Document No.: _____
Iteration No.: _____
Attachment: _____ Page: _____ of _____

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.
HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

1. PURPOSE

The purpose of this Installation Qualification (IQ) protocol is to provide a series of Test Scripts to be used to qualify the installation of any Milford site process equipment and ancillary system to ensure compliance to manufacturer's guidelines and/or Waters requirements.

Once completed, the applicable executed IQ protocol Test Script Data Sheets will be included within an Installation Qualification Report (IQR), which will serve as objective evidence that all key aspects of the equipment and ancillary system are correctly installed.

2. SCOPE

This Installation Qualification protocol shall be used for all equipment within a method or process that makes a decision which can affect product, or that the improper installation and/or configuration would impact the assessment or production of product, as defined in 730001835, Process Validation Procedure for Milford Site.

3. ΔABBREVIATIONS

Term	Definition / Abbreviation
%	Percent
#	Number
°C	Degrees Celsius
Cal	Calibration
CTQ	Critical to Quality
Doc.	Document
EH&S	Environmental Health and Safety
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
WI	Work Instruction

4. ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Engineering Managers	- Ensure implementation of this protocol and affiliated operating procedures. - Review and/or approve all necessary documentation deliverables, as required. - Assign resources as required to support validation activities.
Originator	- Coordinate the execution of the applicable IQ activities. - Author the IQ Report summarizing results, upon completion of IQ activities.
Executor	- Execute applicable IQ activities per instructions from Originator using the applicable Test Scripts. - Responsible for providing the Originator with objective evidence needed to meet the requirements outlined in the applicable Test Scripts. - Follow all GDP requirements per Waters' Good Documentation Practices 730000523.
Reviewer	Review the finalized IQ Report.
Approver	Review and approve the finalized IQ Report.

5. RELATED DOCUMENTS

Doc #	Document Title
730000837	Waters Global Validation Policy
730001833	Test Engineering Management Policy
730001835	Process Validation Procedure for Milford Site
730001799	Operating Procedure, Calibration and Preventive Maintenance
730000295MP	Quality System Document Control
WAT000050MP	Waters Record Retention Corporate Policy
730000523	Waters' Good Documentation Practices
730000483	Global WI/Operating Procedure Template
730002232	Process Validation Master Plan - Milford

6. FORMS/TEMPLATES

Doc #	Document Title
730002845	Validation Report Template

6.1. ΔRecords

The executed Test Script Data Sheets shall be used as objective evidence within the associated IQ Report. The IQ Report shall be stored in SAP in accordance with 730001835, Process Validation Procedure for Milford Site.

7. ΔHEALTH & SAFETY

All personnel performing any part of this IQ shall be trained to this protocol, and/or the operating procedure(s) when applicable, prior to the start of any testing. A Training Record shall be filled out and attached to the associated IQR when training has been performed. A blank Training Record is provided as Appendix A and may be used. If used, the Originator and/or Executor shall digitally edit/enter the Document Number, Document Title, and the Version/Revision/Iteration in the light gray cells.

8. ΔPROCEDURE

The applicable Test Script Data Sheets provided after this Section shall be executed as follows:

- 8.1. The Originator and/or Executor shall digitally edit/enter any descriptive information and acceptance criteria, as applicable, in the light gray cells of the Test Script prior to execution. Rows may be added as needed.
- 8.2. Black text requirements are not to be edited or removed and shall be verified when applicable.
- 8.3. N/A may be entered for any blank parameter or cell that is not used or not applicable.
- 8.4. Blue text examples are provided and should be changed to font color black and/or edited/removed as applicable prior to execution.
- 8.5. Blank and/or unused (blue text) rows may be removed.
- 8.6. The Executor shall perform the applicable Test Scripts, hand writing in all results in the white cells following proper GDP, as defined in 73000523, Good Documentation Practices.
- 8.7. Each page of the applicable Test Script Data Sheets shall have the Report Document Number, Report Iteration, Attachment Number, and be paginated, as defined in 730002845, Report Template.

An example of an IQR Attachment stamp/markings is shown below:

Document No. TE83064-1-IQR
 Iteration No.: 00
 Attachment 8.1 Page: 1 of 1

The stamp shown above is available for use from the Validation Team for unmarked attachments.

8.8. Acceptance Criteria

The IQ will be considered successful when all applicable sections have been completed and an IQR has been written in accordance with 730002845, Validation Report Template, and has been approved. Only the Test Scripts that apply to the Equipment being qualified shall be performed.

Objective evidence will be included in, or attached to, the associated IQR. Examples of objective evidence include, but are not limited to:

- All completed protocol Test Script Data Sheets
- Screenshots
- Calibration/PM Certificates and/or Records
- Photos
- Test reports

8.8.1. Failure to Meet Acceptance Criteria

If the standard IQ execution is not able to be performed follow the following steps:

- If a discrepancy is found which can be resolved, make the change and then continue with the execution. Discrepancies and their resolutions shall be summarized in the Deviation section of the IQR.
- In the event that a discrepancy is not able to be resolved the Originator must decide to either submit the IQR to the appropriate signatories with a recommendation to accept, with justification, or reject the qualification. In the case of a rejected qualification the applicable engineering personnel shall assess the issue and determine if changes can be made in order to move forward with the IQ.

8.9. Installation Qualification Report

- 8.9.1. An Installation Qualification Report shall be written in accordance with 730002845, Validation Report Template, upon completion of all applicable IQ Test Script requirements. The IQR shall summarize the results of the testing performed and any deviations that occurred.
- 8.9.2. ΔThe following Test Scripts shall be used, as applicable, for the execution of the Installation Qualification:

Title: Installation Qualification Protocol

Document # 730004135

Version # 02

Page 4 of 11

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	H2 04 Mar 2019	
CAL	Alliance Heater Cooler Cal/PM Procedure 735004597 (Version 00, Revision A)	Ready	H2 04 Mar 2019	
Comments: N/A JB 04 Mar 2019				
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☒ Pass ☐ Fail				

Objective Evidence: SAP screenshots of below available documents

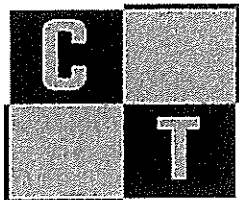
Alliance Heater Cooler Test Procedure 735004582 (Version 00, Revision A)

Document List After Selection 1 Hits									
Waters									
100 5120000 OF 10000 10000000									
Choose Save Thumbnails (Images)									
RevL	Type	Document	Vs	Part Description	Status text	Current Vc	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									
100 5120000 OF 10000 10000000									
Choose Save Thumbnails (Images)									
RevL	Type	Document	Vs	Part Description	Status text	Current Vc	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.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	



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
CUSTOMER :	FLEXTRONICS MANUFACTURING (SINGAPORE) PTE LTD.	Range :	-
		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.	Hydrogen	0061445393	22-Aug-18

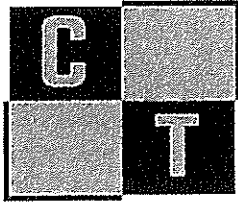
RESULTS OF CALIBRATION :

- The expanded uncertainty of measurement associated with the calibration is estimated at a confidence level of approximately 95 % with a coverage factor of $k=2.00$.
- The results of calibration are given on the attached calibration data sheet(s).
- The user should determine the suitability of the Instrument for its intended use.
- 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
FANFAT CHENG CHAN NIN



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 :

Kyaw Zin Thant

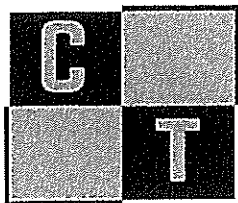
EMP ID : 1068

Approved by :

Anoop Ummappilly

EMP ID : 1039

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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	: 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 :

Kyaw Zin Thant

EMP ID : 1068

Approved by :

Anoop Ummappilly

EMP ID : 1039

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

Test Script # IQ-02

Ambient Temperature: 20°C

flex

SKW-MFG4018-00

Temperature and Humidity Monitoring Record

Rev: A

Form B

(1) Month / Year : <u>Mar 19</u>		(4) Equipment Used : <u>HOB0</u>		(7) EQ ID : <u>1494</u>	
(2) Floor Level : <u>5th Floor</u>		(5) Serial Number : <u>10715936</u>		(8) Temperature Range : <u>18°C to 30°C</u>	
(3) Area : <u>Production</u>		(6) Calibration due date : <u>13 Jun 19</u>		(9) Humidity Range : <u>25%RH to 85%RH</u>	

Date Check	(16) Time Check	Measurement		(15) Within Spec.	(14) Out of Control Record				(21) Name / Signature	(22) NCMR
		(17) Temperature (°C)	(18) Humidity (%RH)		(17) Temperature (°C)	(18) Humidity (%RH)	(19) Date Out	(20) Time Out		
1	0706	20	61	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah g	NA
2	0705	21	59	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah g	NA
3	X	X	X	Yes / No	X	X	X	X	Yep Thim Wah g	X
4	0725	20	61	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah g	NA

Relative Humidity : 61

flex

SKW-MFG4018-00

Temperature and Humidity Monitoring Record

Rev: A

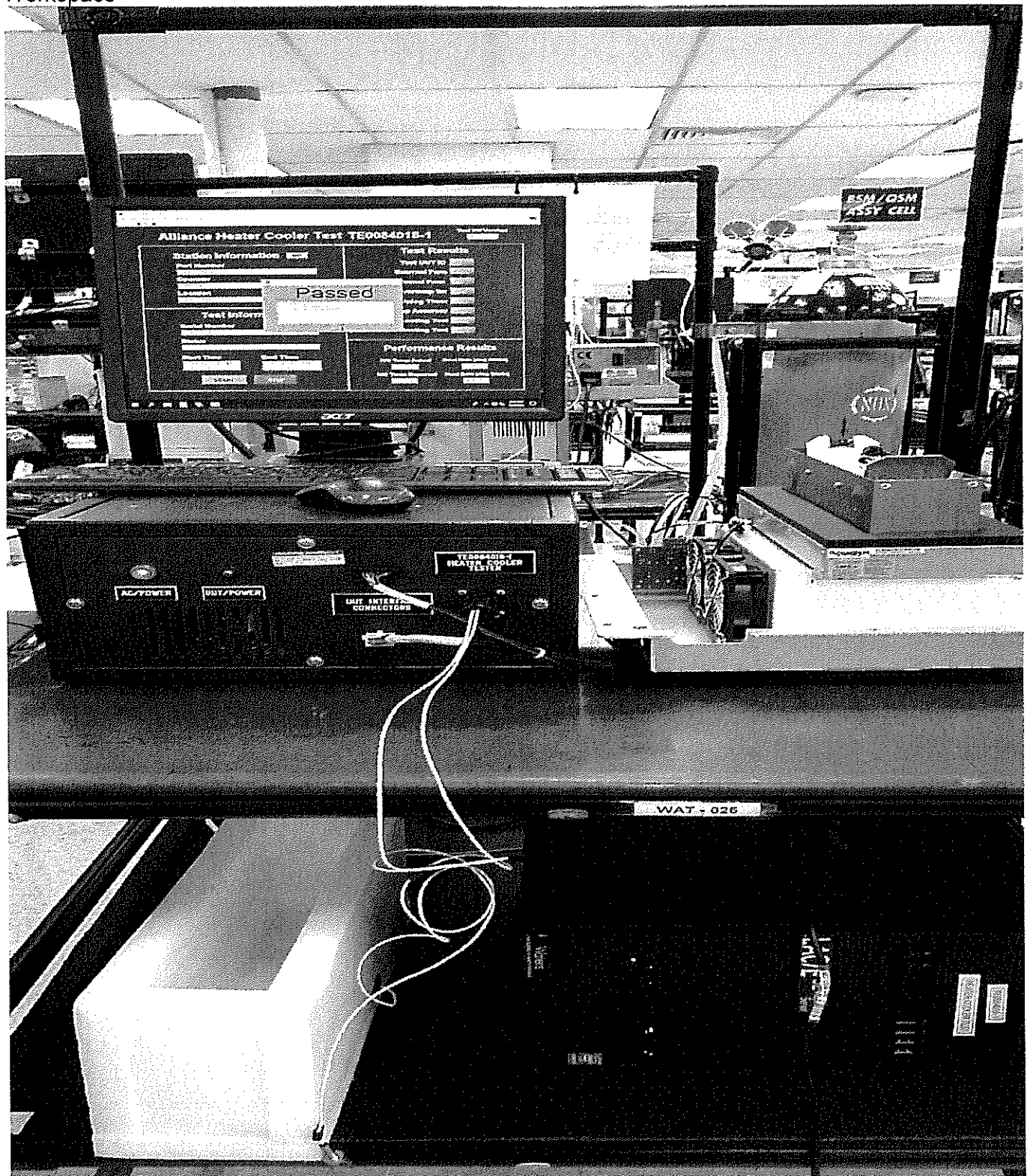
Form B

(1) Month / Year : <u>Mar 19</u>		(4) Equipment Used : <u>HOB0</u>		(7) EQ ID : <u>1494</u>	
(2) Floor Level : <u>5th Floor</u>		(5) Serial Number : <u>10715936</u>		(8) Temperature Range : <u>18°C to 30°C</u>	
(3) Area : <u>Production</u>		(6) Calibration due date : <u>13 Jun 19</u>		(9) Humidity Range : <u>25%RH to 85%RH</u>	

Date Check	(16) Time Check	Measurement		(15) Within Spec.	(14) Out of Control Record				(21) Name / Signature	(22) NCMR
		(17) Temperature (°C)	(18) Humidity (%RH)		(17) Temperature (°C)	(18) Humidity (%RH)	(19) Date Out	(20) Time Out		
1	0706	20	61	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah g	NA
2	0705	21	59	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah g	NA
3	X	X	X	Yes / No	X	X	X	X	Yep Thim Wah g	X
4	0725	20	61	(Yes) / No	NA	NA	NA	NA	Yep Thim Wah g	NA

Test Script # IQ-02

Workspace



Test Script # IQ-02
Test Station Bench





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

CALIBRATION CERTIFICATE

Ref. No. : FMS / 1942

Page : 1 of 5

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

REVIEWED & ACCEPTED
SIGN: CHANG MEI LAN
DATE: 07 JAN 19
REMARKS: FBID 0245
JOEL MANALATO
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 : $(23 \pm 3) ^\circ\text{C}$
Humidity : $(35 \sim 65) \% \text{rh}$

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
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

Muhammad Azuan Bin Ali
Engineer



Approved By

Lim Beng Soon
Senior Manager
02-Jan-2019

shh



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MEASUREMENT REPORT

Page : 2 of 5

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 Vocab in Metrology JCGM 200:2005)

[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



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

MEASUREMENT REPORT

Date : 02 Jan 2019

Ref. No. FMS / 1942

Page : 3 of 5

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



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

MEASUREMENT REPORT

Date 02 Jan 2019

Ref. No. : FMS / 1942

Page : 4 of 5

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



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MEASUREMENT REPORT

Date : 02 Jan 2019

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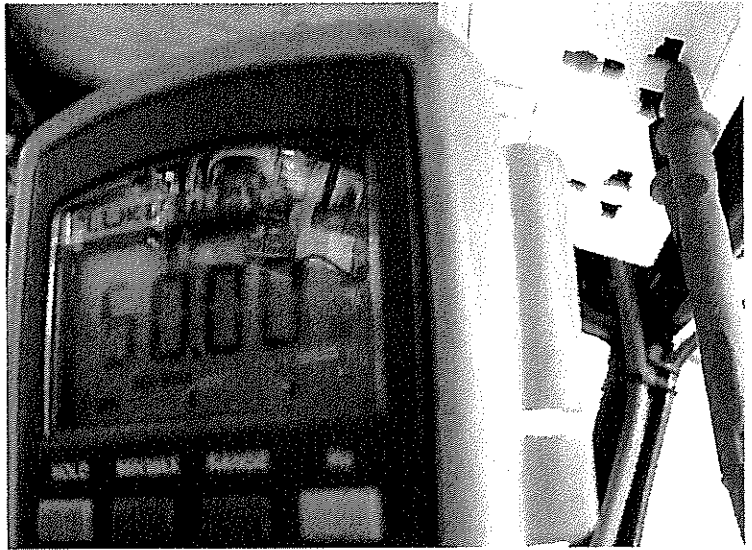
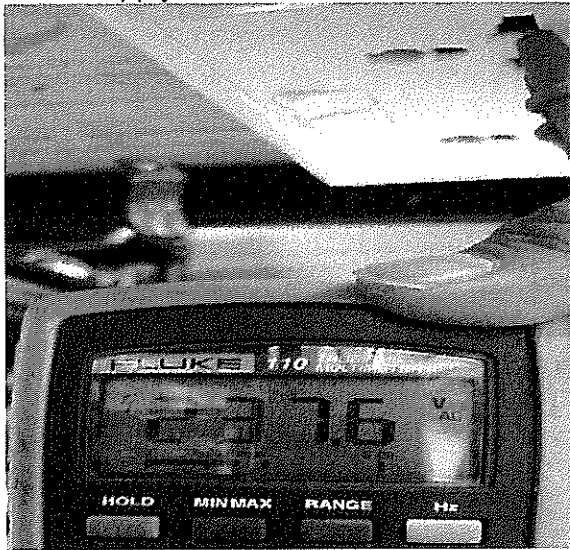
The Expanded Uncertainties of measurement (excluding the uncertainties of the Unit Under Test) for the results given in this report, with a confidence level of approximately 95% at Coverage Factor $k = 2$, are as follows:

Parameters	Range		Uncertainty
AC Voltage Generation	33 ~ 329.999 mV	45 Hz ~ 10 kHz	0.0058 % + 23 μ V
	3.3 ~ 32.9999 V	45 Hz ~ 10 kHz	0.05 % + 693 μ V
	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 μ V
	30 ~ 329.9999 V		0.0064 % + 500 μ V
	100 ~ 1000 V		0.0064 % + 1.5 mV
Resistance Generation	330 ohm ~ 1.09999 k Ω		0.17 % + 0.07 Ω
	3.3 ~ 10.9999 k Ω		0.010 % + 0.7 Ω
	33 ~ 109.999 k Ω		0.013 % + 7 Ω
	330 k Ω ~ 1.09999 M Ω		0.017 % + 63 Ω
	3.3 ~ 10.9999 M Ω		0.07 % + 635 Ω
	11 ~ 32.9999 M Ω		0.12 % + 635 Ω
Capacitance Generation	0.33 ~ 1.0999 μ F		0.29 % + 1.2 nF

Muhammad Azuan Bin Ali

Test Script # IQ-02

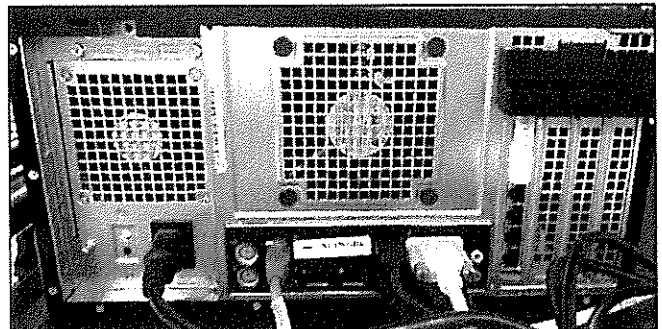
Electrical Supply: 237.6 VAC , 50 Hz



Electrical Outlets



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



Title: Installation Qualification Protocol

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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: 09 Jan 2019 Cal/PM Due: 09 Jan 2020	HZ 04 Mar 2019
Comments: N/A JG 04 Mar 2019			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☒ Pass ☐ Fail			

Title: *Installation Qualification Protocol*

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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	H2 04 Mar 2019	
Comments: NA JG 04 Mar 2019					
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____			
☒ Pass ☐ Fail					

Test Script # IQ-04

Equipment Test Software : Version 0.0

Alliance Heater Cooler Test TE0084018-1 Test SW Version 0.0

Station Information	Test Results
Part Number 289000560	Test UUT ID
Operator 246154	External Fans
Location Flextronics, SG	Internal Fans
	Overtemp Bit
	 watchdog Timer
	Temp Accuracy
	Cooling Test
	Heating Test

Test Information		Performance Results
Serial Number 08K0G045		H/C Temp Actual Cool Rate (deg C/min) 22.2205 -1.909
Status 		H/C Temp Reported Heat Rate (deg C/min) 21.808 4.457
Start Time 2:31:39.754 PM 3/4/2019	End Time 2:47:36.300 PM 3/4/2019	
START STOP		

Test Passed

Unit PASSED Test

1. Disconnect the heater cooler.

2. Click OK to return to the Main GUI

OK

Title: Installation Qualification Protocol

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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	#2 04 Mar 2019
Comments: 			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☒ Pass ☐ Fail			

Title: Installation Qualification Protocol

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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: 08K0G045	All required CTQ Specification measurements result in a Pass	Pass	HZ 04Mar2019
Comments: 			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☒ Pass ☐ Fail			

Test Script # IQ-06

Part Number: 289000560
Serial Number: 08K0G045

Windows Explorer - C:\Program Files\Alliance

File Edit Operate Tools Window Help

Alliance Heater Cooler Test TE0084018-1

Test SW Version 0.0

Station Information

Part Number: 289000560

Operator: 246154

Location: Flextronics, SG

[EDIT](#)

Test Results

Test UUT ID:

External Fans:

Internal Fans:

Overtemp Bit:

Watchdog Timer:

Temp Accuracy:

Cooling Test:

Heating Test:

Test Information

Serial Number: 08K0G045

Status:

Start Time: 2:31:39.754 PM 3/4/2019

End Time: 2:47:36.300 PM 3/4/2019

[START](#) [STOP](#)

Performance Results

H/C Temp Actual	Cool Rate (deg C/min)
22.2205	-1.909
H/C Temp Reported	Heat Rate (deg C/min)
21.808	4.457

Test Passed

Click OK to End Test

1. Click OK to return to the Main (UI)

2. Click OK to return to the Main (UI)

[OK](#)

3:00 PM 3/4/2019

DOCUMENT HISTORY

VERSION:	02	ORIGINATOR:	James Stors	Change ID:	N/A
SUMMARY OF CHANGE: Edited for overall grammar and terminology. Updated the Abbreviation section. Changed Performer to Executor. Updated the Records section to reference 730001835. Added Health & Safety Section. Section 8 updated to guide the Originator to type in descriptive/acceptance criteria in the Test Script Data Sheets and Training Form. Test Script Data Sheets updated to utilize gray cells for guidance and to provide a specified location for the Attachment Stamp/Marking. Removed blank rows from the Test Script Data Sheets. Removed the Electrical Safety Hi Pot/Ground Continuity test from IQ-05 Test Script Data Sheet. Added additional safety considerations to the Test Execution of IQ-05 Test Script Data Sheet. Added the Document Control Section marking to the Test Script Data Sheets and the Training Record appendix.					