

VALIDATION ASSESSMENT

For the name of the 2690 Heater / Cooler PCB FCT Fixture (TE0084014)

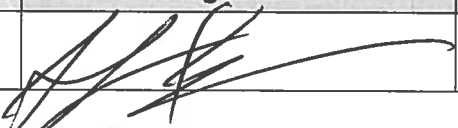
PREPARED BY

Name	Role	Signature	Date
Tyler Modelski	Test Engineer II		26 Feb 2019

REVIEWED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		26 Feb 2019

APPROVED BY

Name	Role	Signature	Date
Andre Kopyan	Sr. Ops. Quality Engineer		28 Feb 2019

The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

The "Reviewed By" signature[s] denotes agreement with the details of the planned testing and/or deliverables to be performed in order to verify the name of the 2690 Heater / Cooler PCB (TE0084014).

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

1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the released 2690 Heater / Cooler PCB FCT Fixture (TE0084014). This document shall also define the deliverable(s) required to maintain the equipment qualification, based on the engineering change. Verification of the equipment shall ensure that it functions within its specifications.

2. BACKGROUND

The 2690 Heater / Cooler PCB Functional Test Fixture (TE0084014) is a custom wired vacuum fixture that is hosted on the Global Test System (TE82988) with Virginia Panel Interface. The system is programmed using NI TestStand 4.2.1 and NI LabVIEW 2009 to control test automation. The fixture is used for functional testing of PCB Assembly P/N 210000444 and 210000150. These PCBs are functionally equivalent, the only difference being P/N 210000444 is RoHS compliant. The performance specifications (810000150 & 810000444) of these two boards are equivalent.

The test equipment verifies functionality of the following circuits:

1. UUT Power
2. Status Bits
3. External Fans
4. Internal Fans
5. Heater/Cooler Drive
6. Thermistor
7. LED Indicators

3. DESCRIPTION OF CHANGE.

- 3.1. Upon transfer of the TE0084014 fixture to Flextronics in Singapore, there were repeated test failures occurring during the External Fans testing; specifically, the Test Pump Fan Tach test step. An investigation was performed and it was determined that the test specification needs to be changed from 107 Hz – 115.5 Hz to 100 Hz – 128 Hz. Refer to Attachment #1 for details and justification of the specification change.

4. RISK ASSESSMENT**4.1. High Risk Assessment**

Please check the appropriate boxes below to determine the high risk assessed qualification or requalification requirements:

4.1.1. Specification	No	Yes
Is the change a test specification value being modified and/or added?	☐	☒

4.1.2. Software/Firmware	No	Yes
Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
Is the change due to firmware downloaded to the UUT by a test system?	☒	☐
Is the change a flash file update?	☒	☐
Is it a change to an existing, or the addition of a new, PCB Test Sequence?	☐	☒

4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

4.1.4. Equipment/Process Moves

No

Yes

Is the change a move of the equipment, test method or process, to a different facility?

☒

☐

4.2. Medium Risk Assessment

Please check the appropriate boxes below to determine the medium risk assessed qualification or requalification requirements:

4.2.1. Replacement of Non-Identical

No

Yes

Is the change due to a replacement of a system component with a non-identical equivalent?

☒

☐

4.2.2. Computer Related or Replacement of Custom PCBs

No

Yes

Is the change an update to the PC operating system?

☒

☐

Is the change a computer or printed circuit board replacement?

☒

☐

4.2.3. Software/Firmware

No

Yes

Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?

☒

☐

Is the change a test system instrument firmware update (i.e. update to a stack component)?

☒

☐

4.2.4. Equipment/Process Moves

No

Yes

Is the change a move of the equipment, test method or process, within the Milford site?

☒

☐

4.3. This change results in a High Risk Assessment and the associated requalification requirements, as detailed in Section 6.0.

5. HAZARD ASSESSMENT:

There are no hazards potentially introduced to the environment, operator, assembler, service technician or end user due to the change.

6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

6.1. Equipment Design Verification (EDV)	No	Yes
Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?	☐	☒
Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification The EDV protocol for this test fixture must be updated to include the new test specification. The EDV protocol does not need to be executed, as the test method regarding the specification change has not been updated. It has already been verified that the software successfully identifies failures below and above the limits (see TE0084014-EDVR Iteration 00) and the ability to do so is not dependent on the values of the specification limits themselves. It is not necessary to re-run those verification steps. This change can be verified as part of this VAF by attaching a test record from SigmaSure showing the new specification and approving the objective evidence completion form.		

6.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification An IQ does not need to be executed due to this change. This change can be verified as part of this VAF by attaching a test record from SigmaSure showing the new specification and approving the objective evidence completion form.		

6.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification There are no test method changes as part of this update; therefore, there is no TMV required.		

6.4. Operational Qualification (OQ)	No	Yes
Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an OQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification 100% critical to quality (CTQ) attributes are verified, there is no OQ required.		

6.5. Performance Qualification (PQ)	No	Yes
Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does a PQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification 100% critical to quality (CTQ) attributes are verified, there is no PQ required.		

6.6. Electromagnetic Interference (EMI) Assessment:

This change only affects test equipment; therefore, there is no impact to product EMI.

7. IMPLEMENTATION ASSESSMENT:

- Test engineer will update the test code with the specification change.
- Test engineer will install the test code on the GTS at Flextronics and take a screenshot of the new software version.
- A test will be performed on the GTS at Flextronics and the test record obtained from SigmaSure.
- The test software version screenshot and test record is attached to this VAF and the objective evidence approval form signed off.

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document #: TE0084014-25FEB19-VAF	SAP #: TE0084014QX

VALIDATION ASSESSMENT
OBJECTIVE EVIDENCE COMPLETION
For the 2690 Heater / Cooler PCB FCT Fixture (TE0084014)

PREPARED BY

Name	Role	Signature	Date
Tyler Modelski	Test Engineer II		20 Aug 2019

REVIEWED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		26 Aug 2019

APPROVED BY

Name	Role	Signature	Date
Megan Marshall	Sr. Quality System Engineer		26 Aug 2019

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The below Attachments section is used to list all attachments that will serve as objective evidence, as required by this Validation Assessment Form.

ATTACHMENTS:

- Attachment 1: Justification : Test Pump Fan Tach ON – Specification Change
- Attachment 2: Additional Justification: Test Pump Fan Tach ON – Specification Change
- Attachment 3: Screenshot of Test Software Version 0.1
- Attachment 4: Copy of UUT Test Record

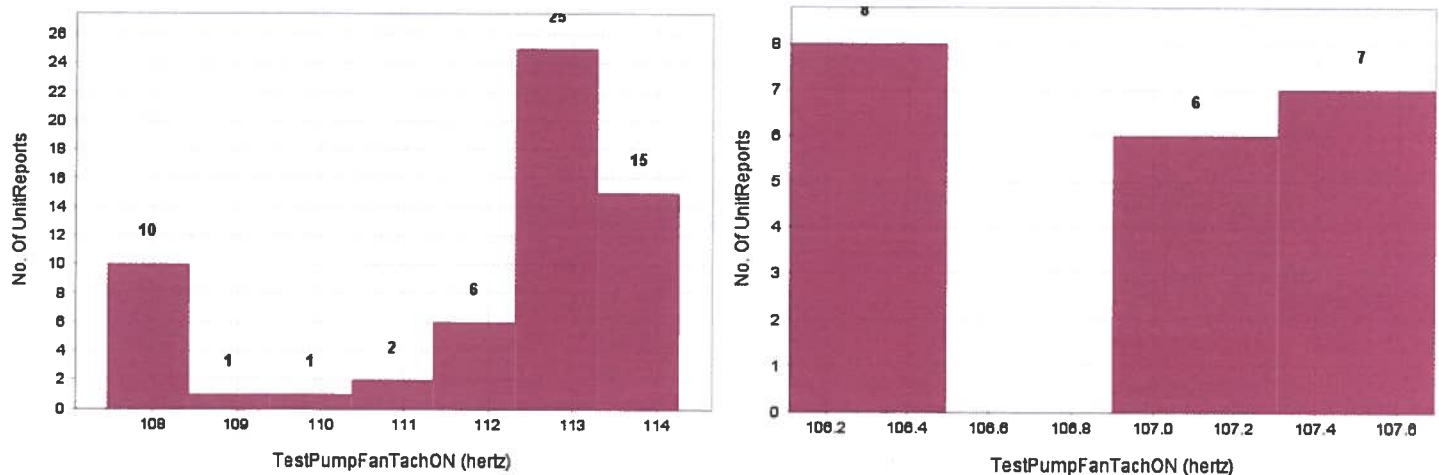
Justification: Test Pump Fan Tach ON – Specification Change

After the transfer of the TE0084014 test fixture, a set of “known good boards,” previously verified using an old manufacturing test, were tested on the new fixture. The old manufacturing test uses a different test method by checking for a pump fan tach error and not the frequency of the signal. The new test verifies the frequency of the pump fan tach signal. It was found that the Pump Fan Tach ON test was consistently failing for one of the UUTs at just below the LSL of 107 Hz (see screenshot of test record below).

Test Ext Fan Control

VerifyStartupFan1&2						FAIL
TestExtFanFailBitClr						DONE
Test Fan1 is ON	23.5	23.988	24.1	volt	PASS	PASS
Test Fan2 is ON	23.5	24	24.1	volt	PASS	PASS
TestPumpFanTachON	107	106.450926	115.5	hertz	FAIL	FAIL

This failure was not seen during the development phase or during the equipment design verification (EDV). During that time, all test measurements fell between the specification range of 107 Hz – 115.5 Hz (see distribution below on the left). However, once the fixture was transferred to Flextronics in Malaysia, it was found that all of the known good boards test measurements were falling on the lower end of the specification range (see distribution below on the right), with the board under question falling outside the range.



This indicated that the specification range may be too tight. The performance specifications for the UUT (810000444 and 810000150) were reviewed and it was determined that the specification should be **100 Hz – 128 Hz** based on the tolerances specified (see next page).

The below screenshots from the performance specification indicate that the Pump Fan Tach Signal is the FAN_CLK signal divided down to 114 Hz. The tolerance on the FAN_CLK signal is 12% at 903 Hz. To calculate the proposed specification, the lower and upper FAN_CLK frequencies were calculated and then divided by the same divisor used to obtain the target 114 Hz.

$$\text{Divisor} = 903 \text{ Hz} / 114 \text{ Hz} = 7.91$$

$$\text{FAN_CLK Lower} = 903 \text{ Hz} - 903 \text{ Hz} (0.12) = 794.64 \text{ Hz}$$

$$\text{FAN_CLK Upper} = 903 \text{ Hz} + 903 \text{ Hz} (0.12) = 1011.36 \text{ Hz}$$

$$\text{Proposed LSL} = 794.64 \text{ Hz} / 7.91 = 100.32 \text{ Hz}$$

$$\text{Proposed USL} = 1011.36 \text{ Hz} / 7.91 = 127.68 \text{ Hz}$$

This results in a specification range of 100.32 Hz – 127.68 Hz. This signal is used to tell the Pump Driver board in the Alliance system that there is not an external fan failure. The detection limit for the board is approximately greater than 50 Hz (as highlighted below); therefore, testing to the specification range of 100 Hz – 128 Hz ensure the signal is higher than the fan failure detection limit in the final instrument.

Performance Specification Screenshots:

2.3.6 TIMING CIRCUITS FOR FAN FAIL AND WATCH DOG TIMER

The two clocks, **FAN_CLK 903 HZ @12% tolerance** and **CLK1SEC 1 HZ @ 22% tolerance** are generated from the 556 dual timer IC. Each section of the 556 utilizes two resistors and a capacitors. The major tolerance errors come from the tolerance of the capacitors used. The two clock outputs are both Schmitt Triggered before they enter the EPLD.

2.3.7 SIMULATED FAN TACH SIGNAL FOR PUMP DRIVER PCB

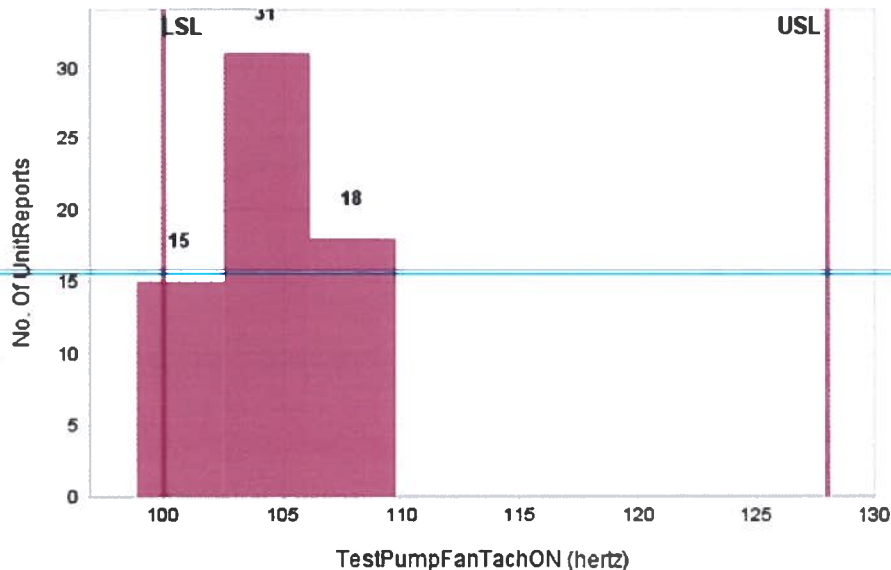
The signal **PMPFAN** (which originates in the EPLD, then goes to an Opto-Isolator, then to the 2x9x Pump Driver PCB) is simply **FAN_CLK divided down to about 114 HZ**. The EPLD generates this signal as long as there hasn't been two External Fan Failures. The signal **PMPFAN** is active when one or both external fans are operating normally. **As long as the frequency of PMPFAN is greater than the Pump Driver PCB detection frequency (~50 HZ)** the 2x9x Pump Driver PCB will view this as a normally operating fan.

Table Summarizing Proposed Specification Calculations:

	Frequency (Hz)	Tolerance (%)	Lower (Hz)	Upper (Hz)
FAN_CLK	903	12%	794.64	1011.36
	Target Frequency (Hz)	Divisor	Proposed LSL (Hz)	Proposed USL (Hz)
PMPFAN	114	7.921052632	100.32	127.68
			Current LSL (Hz)	Current USL (Hz)
			107	115

Additional Justification: Test Pump Fan Tach ON – Specification Change

After performing the verification steps outlined in the validation assessment form, it was found that the specification limits still remained too tight. The verification run involved testing 50 boards to the specification of 100 – 128 Hz, which resulted in 4 failing just below the 100 Hz LSL. See a screenshot of the histogram of the results below:



19-Aug @ 01:46 PM

As stated in the performance specification for the 210000444 PCB, **as long as the pump frequency is greater than the detection threshold of 50 Hz**, the unit will see this as a properly operating fan. See the screenshot below of the performance specification. The LSL for this test should be 50 Hz.

Performance Specification Screenshots:

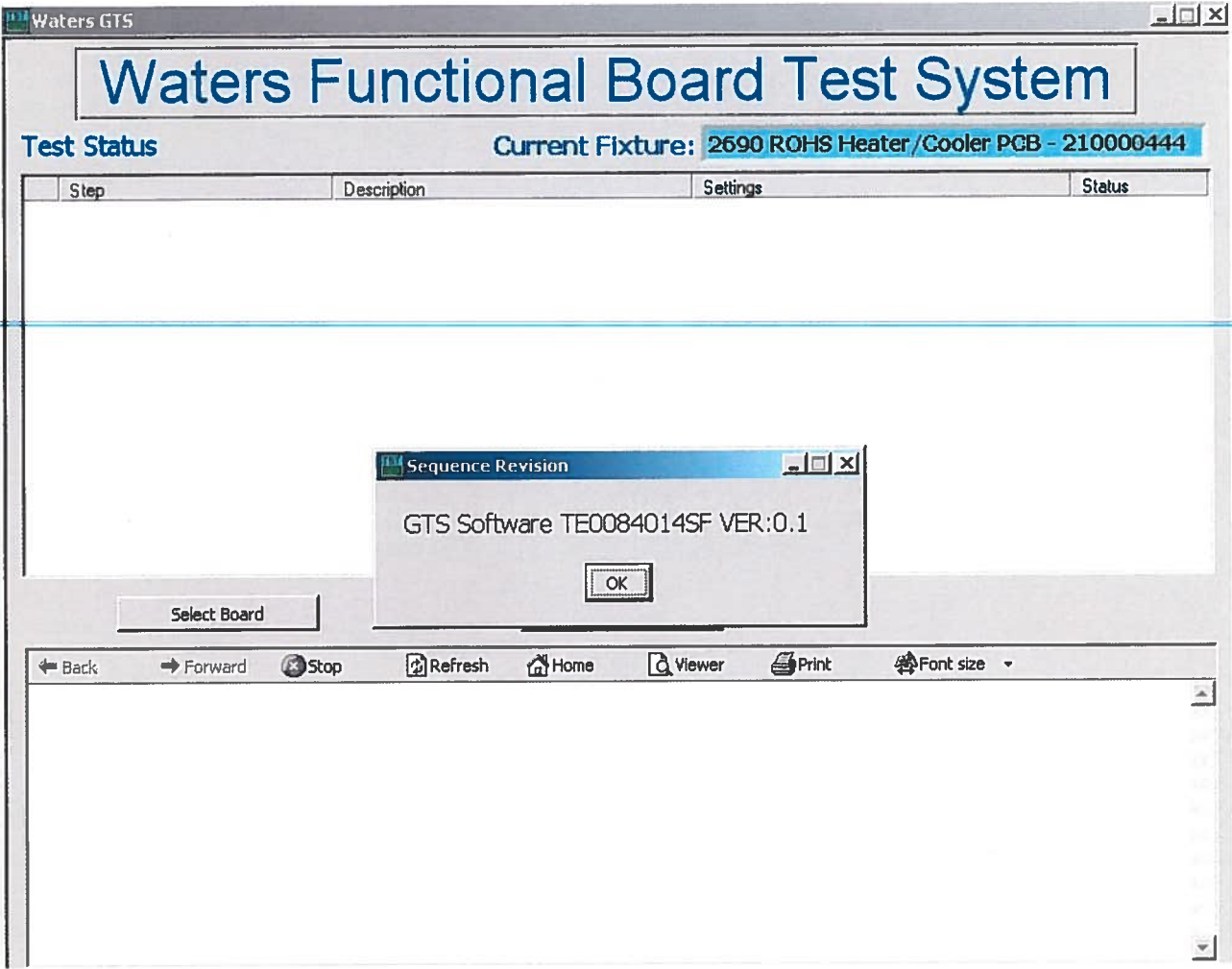
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The signal **PMPFAN** (which originates in the EPLD, then goes to an Opto-Isolator, then to the 2x9x Pump Driver PCB) is simply **FAN_CLK divided down to about 114 HZ**. The EPLD generates this signal as long as there hasn't been two External Fan Failures. The signal **PMPFAN** is active when one or both external fans are operating normally. **As long as the frequency of PMPFAN is greater than the Pump Driver PCB detection frequency (~50 HZ)** the 2x9x Pump Driver PCB will view this as a normally operating fan.

Screenshot TE0084014 Test Software Version 0.1



Waters Corporation - Test Record

Part Number: 210000444

Product:

Operator: administratorStart Time: 08/19/2019, 15:19:45Serial Number: 090616803MEnd Time: 08/19/2019, 15:21:32Test System: TE82988-6

Name	LSL	Measurement	USL	Unit	Outcome
ValidSerialNumber					PASS
Vacuum					PASS
Test UUT Power					PASS
CheckPowerStatus					PASS
CheckQuCurrent					DONE
TestCurrent24V	0.15	0.206	0.3	ampere	PASS
TestCurrentVCC	0.1	0.132	0.2		PASS
TestCurrent5VA	0	0	0.01		PASS
Test 12V Supply	10.5	10.982	11.5		PASS
Test Status Bits					PASS
TestCmdReadBack					PASS
TestIStatusBitsInitialState					PASS
Test OverTemp Bit Off					PASS
Test OverTemp Bit On					PASS
Test OverTemp Bit is Cleared					PASS
Test WatchDog Bit is Off					PASS
Test WatchDog Bit after 6 Seconds					PASS
Test WatchDog Bit after 12 Seconds					PASS
Test WatchDog Bit is Cleared					PASS
Test Ext Fan Control					PASS
VerifyStartupFan1&2					DONE
TestExtFanFailBitClr					PASS
Test Fan1 is ON	23.5	23.998	24.1	volt	PASS
Test Fan2 is ON	23.5	24.006	24.1	volt	PASS
TestPumpFanTachON	50	112.714156898	128	hertz	PASS
TestExtFanFailBitSet					PASS
TestPumpFanTachOFF	-0.1	0	0.1	hertz	PASS
VerifyFailClrFan1&2					DONE
TestPumpFanTachBackON	50	112.764997745	128	hertz	PASS
TestExtFanFailBitClr					PASS
Test Int Fan Control					PASS
TestIntFanOutputOFF	-1	Measured Volts, Current, Power Channel 10	1	volt	PASS
TestIntFanOutputOn	10	Measured Volts, Current, Power Channel 111.194	12	volt	PASS
TestIntFanFailBitSet					PASS
TestIntFanOutputForcedOFF	NaN	Measured Volts, Current, Power Channel 10		volt	PASS
TestIntFanFailBitClr					PASS

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TestIntFanOutputBackOn	10	Measured Volts, Current, Power Channel 111.185	12	volt	PASS
Test Heater/Cooler Drive					PASS
Heat Off [No Output]					DONE
Test Heater Init Off	-0.1	0.002	0.1	volt	PASS
Heat On && H-Bridge Off [No Output]					DONE
Test Heater Still Off	-0.1	0.002	0.1	volt	PASS
Heat On && H-Bridge On [Neg Output]					DONE
Test Heater On	-24.5	-23.65	-23.5	volt	PASS
Heat Off && H-Bridge On [No Output]					DONE
Test Cooler Init Off	-0.1	0.011	0.1	volt	PASS
Cool On && H-Bridge On [Pos Output]					DONE
Test Cooler On	23.5	23.647	24.5	volt	PASS
Cool Off && H-Bridge On [No Output]					DONE
Test Cooler Off	-0.1	0	0.1	volt	PASS
Test Thermistor Input					PASS
Test @ 0 degrees	-1	0	1		PASS
Test @ 25 degrees	24	24.801380392	26		PASS
Test @ 40 degrees	39	40.108482353	41		PASS
Test Inticators					PASS
CoolIndTest					PASS
FanIndTest					PASS
HeatIndTest					PASS
Vacuum OFF(Fixture Up)					DONE

210000444 Overall Result - PASS

Signed: *TJM* Date: *19 Aug 2019*

END OF DATA

Record printed from Signature. TJM 20 Aug 2019

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