MODALITY solutions™	COLDBOX express		**Report**
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TITLE **Cold Box Studies; Box 111412**			

APPROVALS

MODALITY SOLUTIONS ENGINEERING		
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ABBREVIATIONS AND DEFINITIONS

ISTA	International Safe Transit Association
LTL	Less-than-truckload. A shipment that does not require a full 48- or 53-foot trailer can be shipped via less-than-truckload.
N/A	Not Applicable
OQ	Operational Qualification
SOP	Standard Operating Procedure
TC	Thermal Couple
VIP	Vacuum Insulation Panel

SUMMARY

The Cold Box is intended for the shipment of temperature labile product. The studies summarized here were conducted to show that the Cold Box is capable of maintaining a range of set points, depending on product requirements for at least four days without need for re-charging. Payload for these tests consisted of empty corrugated boxes. These empty corrugated boxes represent a minimal cube capacity for the shipper as well as a minimal thermal mass and therefore challenged the ability of the Cold Box to maintain uniform temperatures within the product payload area.

Cold Box number 111412 was tested at an independent thermal laboratory. This report describes the thermal performance testing of the unit (five separate studies) for use in an LTL environment for the shipment of temperature labile product. The studies were conducted at GH Testing in Cincinnati, OH between April and May 2015.

The results of this study indicate that the Cold Box when fully charged is capable of maintaining the selected setpoint for at least 4 days when exposed to the typical extremes expected in an LTL environment. It is critical to operation that the Cold Box be charged for at least 12 hours prior to the commencement of preconditioning. The data collected from the testing is presented in Appendix 7 of this report. The results from this report support the preparation of Performance Qualification (PQ) activities.

1. PURPOSE

This master report covers five specific studies that were conducted to demonstrate the performance of the Cold Box active shipper. The studies are summarized in three reports, autonomous operation, limit testing, and battery charge.

The Cold Box is intended for the shipment of temperature labile product. The studies that were conducted show that the Cold Box is capable of maintaining a range of set points, depending on product requirements. Payload for the tests consisted of empty corrugated boxes. As planned, empty corrugated boxes represented the minimal cube capacity of the shipper as well as a minimal thermal mass and challenged the ability of the Cold Box to maintain uniform temperatures within the product payload area.

The five studies conducted are listed below:

1. Autonomous Operation-Hot, five days, (or until the interior temperature exceeds 8C), set point +5C

2. Autonomous Operation-Cold, five days, (or until the interior temperature exceeds 2C) set point +5C

3. Limit Testing-Hot, 24 hours, Cold Box set point -20C, Chamber set point 35C, increasing in 5C increments

4. Limit Testing-Cold, 24 hours, Cold Box set point 20C, Chamber set point -20C, decreasing in 5C increments

5. Battery Charge Test: Ambient, 8 hours

2. INTRODUCTION

CBX Manufacturing produces the Cold Box active pallet shipper. The specification for the shipper is included in Appendix 1. The Cold Box has a tare weight of 1,850 lbs. The outer dimensions are 49” x 80” x 82”h. The inner payload is 43.6”x 51.1 x 61”h. The shipping container is constructed of a 1” vacuum insulation panel (VIP) assembly with additional foam layers intended to provide long-term protection the VIP. The VIP assembly creates a thermal barrier that keeps the payload contents at a constant temperature longer. A bank of batteries that supply power to a cooling compressor and a resistive heating element powers the shipper and a master control supervises the overall operation of the Cold Box.

The payload test configuration that was used for all testing of the Cold Box shipper included eight empty corrugated boxes secured to a 42” X 48” pallet. This arrangement provided for the maximum challenge for air distribution with the Cold Box while minimizing any favorable effects from the presence of significant thermal mass. A test rack supplied by CBX was used to support temperature monitors to record points around the test load while monitors inside the corrugated boxes were used to obtain thermal conditions that would be the expected product exposure.

Figure 1 is a photo (courtesy of Cold Box) showing the pallet shipper ready to load.

Figure 1 Cold Box

3. MATERIALS AND METHODS

3.1. Equipment and Supplies

The equipment used in this study is listed in Table 1. Copies of equipment calibration certificates and references to any other additional equipment used can be seen in Appendix 3.

Table 1 Equipment List

Equipment	Calibration Required (Yes/No)	Calibration Due Date
Cold Box SN:111412	No	N/A
Large Temperature Test Chamber (Chamber #2)	Yes	6/6/2015
Type T-Thermocouple	Yes	Performed Pre and Post Studies
Omega Recording System	Yes	
OMEGA Temperature Bath with Heater and Refrigeration unit	Yes	6/5/2015

The supplies used for all studies are presented in Table 2.

Table 2 Supply List and Conditioning Requirements

Materials	Quantity	Conditioning Requirements
CBX Internal Test apparatus (TC positioning)	1	Ambient Room Temperature
Corrugated Boxes	8	
42” X 48” pallet	1	

3.2. Methods

Testing was performed using the methods listed in Table 3. This method is in alignment with CBX -02-0119-01 Temperature Probe Calibration.

Table 3 Methods

Document Owner	Document Number	Document Title
GH Testing	WKI-5.4.49	Calibration Check of TCs; Pre & Post Test
Modality Solutions	LAB-FORM-0001-04	Temperature Logger Calibration Check Form

4. TEST PROCEDURES

Note: All settings of the Cold Box were in °C. The adjustable dead band was 1°C for all testing.

4.1. Pre-Test Thermocouple Calibration Check

Calibration of all TCs was performed pre testing according to WKI-5.4.49- Calibration Check Procedure. All TCs used in the test registered within ±0.5°C of reference values. Thermocouples were checked for calibration at -10°C, 10°C and +30°C. The results were recorded in LAB-FORM-0001-04, Temperature Logger Calibration Check Form, which can be seen in Appendix 4.

Table 4 Thermal Exposures Table

Test	Thermal Exposure
Autonomous Operation	Hot; ISTA 7E; 99% Confidence Interval: Five days
	Cold; ISTA 7E; 99% Confidence Interval: Five days
Thermal Limit Testing	Hot: 35°C for 24 hours; followed by 5°C steps, each lasting 2 hours until failure or maximum chamber temperature is reached
	Cold: -20°C for 24 hours; followed by 5°C steps, each lasting 2 hours until failure or -35°C is reached.
Battery Test	General warehouse conditions

Figure <>2 is showing the supplied frame and the locations used to locate TCs within the Cold Box.

Figure 2 Thermocouple Frame Locations

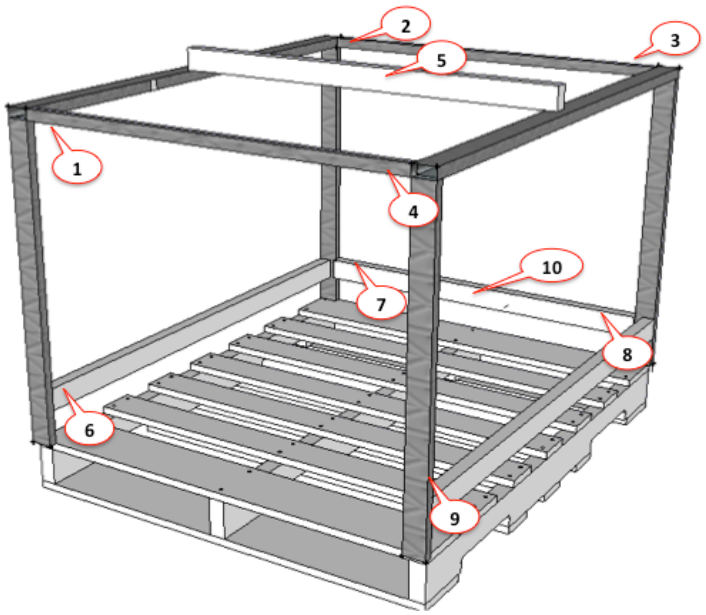


Table 5 Thermocouple Placement

Thermocouple		Location
Frame	Locations 1-5	1-4; Upper Corners; 5 Supply Air
	Locations 6-10	6-9; Lower Corners; 10 Return Air
Corrugated Cartons (not shown)	Locations 11-18	TCs located 2 per carton in each corner carton (4 locations)
Ambient	Locations 19-20	Within chamber to monitor ambient

4.2. Study Design: Autonomous Operation (Hot and Cold)

The autonomous studies were intended to define the duration in which the Cold Box active pallet shipper can maintain refrigerated (2°C to 8°C) conditions. The study consisted of a hot and cold test. Each test was run until the temperature within the unit exceeded refrigerated condition or at least 5 days of testing. The protocol checklist associated with this study, for both the hot and the cold test, can be found in Appendix 5a.

The Cold Box was placed in the thermal test chamber for each autonomous test. The thermal profile is listed in Table 5. Data was recorded at 10 minutes intervals. As specified in Table 5, two ambient TCs were placed in the chamber to monitor chamber temperature. The ambient TCs were positioned such that they did not contact the container. The Cold Box was placed at least 6” away from the chamber walls per ISTA Guidelines (Standard 20).

Table 6 Thermal Profiles for Autonomous Testing

ISTA 7E Heat Profile 99% Confidence Interval (168 Hours)							
Elapsed Time	Temperature (°C)	Elapsed Time	Temperature (°C)	Elapsed Time	Temperature (°C)	Elapsed Time	Temperature (°C)
0	30.7	42	27.2	84	27.6	126	31
1	31.7	43	28.5	85	27.1	127	30.4
2	32.5	44	29.7	86	26.8	128	29.8
3	32.6	45	30.5	87	26.7	129	29.2
4	32.1	46	31.4	88	26.7	130	28.6
5	31.5	47	32	89	26.5	131	28.1
6	30.7	48	32.5	90	27.2	132	27.6
7	29.9	49	32.9	91	28.5	133	27.1
8	29.2	50	33	92	29.7	134	26.8
9	28.7	51	32.9	93	30.5	135	26.7
10	28.1	52	32.4	94	31.4	136	26.7
11	27.8	53	31.7	95	32	137	27
12	27.5	54	31	96	32.5	138	27.7
13	27	55	30.4	97	32.9	139	28.8
14	26.5	56	29.8	98	33	140	29.9
15	26.2	57	29.2	99	32.9	141	30.8
16	26	58	28.6	100	32.4	142	31.6
17	26.2	59	28.1	101	31.7	143	32.1
18	26.8	60	27.6	102	31	144	32.6
19	27.8	61	27.1	103	30.4	145	32.9
20	28.9	62	26.8	104	29.8	146	33
21	29.8	63	26.7	105	29.2	147	32.9
22	30.3	64	26.7	106	28.6	148	32.4
23	30.9	65	26.5	107	28.1	149	31.7
24	31.5	66	27.2	108	27.6	150	31
25	31.9	67	28.5	109	27.1	151	30.4
26	32	68	29.7	110	26.8	152	29.8
27	31.9	69	30.5	111	26.7	153	29.2
28	31.5	70	31.4	112	26.7	154	28.6
29	31.1	71	32	113	26.5	155	28.1
30	30.4	72	32.5	114	27.2	156	27.6
31	29.8	73	32.9	115	28.5	157	27.1
32	29.2	74	33	116	29.7	158	26.8
33	28.8	75	32.9	117	30.5	159	26.7
34	28.3	76	32.4	118	31.4	160	26.7
35	27.9	77	31.7	119	32	161	26.5
36	27.5	78	31	120	32.5	162	27.2
37	27.1	79	30.4	121	32.9	163	28.5
38	26.8	80	29.8	122	33	164	29.7
39	26.5	81	29.2	123	32.9	165	30.5
40	26.5	82	28.6	124	32.4	166	31.4
41	26.5	83	28.1	125	31.7	167	32
						168	32.5

Table 6, continued- ISTA 7E Cold Profile 99% Confidence Interval (168 Hours)							
Elapsed Time	Temperature (°C)	Elapsed Time	Temperature (°C)	Elapsed Time	Temperature (°C)	Elapsed Time	Temperature (°C)
0	11.3	42	0.2	84	0.4	126	-1
1	10.8	43	-0.9	85	2.4	127	-1.2
2	9.8	44	-0.9	86	1.9	128	-1.5
3	9.2	45	-0.4	87	1.4	129	-1.7
4	8.5	46	-0.2	88	1	130	-1.7
5	7.3	47	0.2	89	0.7	131	-1.8
6	6.4	48	0.4	90	0.7	132	-1.9
7	5.7	49	2.4	91	1.1	133	-1.9
8	4.8	50	1.9	92	2.1	134	-1.7
9	4.1	51	1.4	93	2.9	135	-1.6
10	3.8	52	1	94	3.4	136	-1.7
11	3.3	53	0.7	95	4.1	137	-1.7
12	2.9	54	0.7	96	4.8	138	-1.5
13	2.4	55	1.1	97	4.7	139	-1.1
14	1.9	56	2.1	98	4.6	140	-0.4
15	1.4	57	2.9	99	4.3	141	0.4
16	1	58	3.4	100	3.9	142	1.5
17	0.7	59	4.1	101	3.4	143	2.5
18	0.7	60	4.8	102	3	144	2.8
19	1.1	61	4.7	103	2.7	145	0.3
20	2.1	62	4.6	104	2.5	146	0.1
21	2.9	63	4.3	105	2.3	147	0
22	3.4	64	3.9	106	2.4	148	-0.2
23	4.1	65	3.4	107	2.1	149	-0.6
24	4.8	66	3	108	1.7	150	-1
25	4.7	67	2.7	109	1.2	151	-1.2
26	4.6	68	2.5	110	1.3	152	-1.5
27	4.3	69	2.3	111	1.6	153	-1.7
28	3.9	70	2.4	112	1.8	154	-1.7
29	3.4	71	2.1	113	1.2	155	-1.8
30	3	72	1.7	114	0.2	156	-1.9
31	2.7	73	1.2	115	-0.9	157	-1.9
32	2.5	74	1.3	116	-0.9	158	-1.7
33	2.3	75	1.6	117	-0.4	159	-1.6
34	2.4	76	1.8	118	-0.2	160	-1.7
35	2.1	77	1.2	119	0.2	161	1.2
36	1.7	78	0.2	120	0.4	162	0.2
37	1.2	79	-0.9	121	0.3	163	-0.9
38	1.3	80	-0.9	122	0.1	164	-0.9
39	1.6	81	-0.4	123	0	165	-0.4
40	1.8	82	-0.2	124	-0.2	166	-0.2
41	1.2	83	0.2	125	-0.6	167	0.2
						168	0.4

4.3. Study Design: Limit Testing (Hot and Cold)

The limit studies were intended to define the ambient conditions that cause the Cold Box point of failure. Power was supplied to the Cold Box and then conditioned to 35°C (hot) and -20°C (cold) for 24 hours. At that point, the chamber temperature was increased/decreased in 5°C increments to determine the failure point. The protocol checklist associated with this study, for both the hot and the cold test, can be found in Appendix 5b. The Cold Box active pallet shipper was placed into a thermal testing chamber for the duration of the testing.

4.4. Results and Discussion: Battery Charge

With a fully depleted battery, the Cold Box was connected to power and the percent charge was recorded every hour. Battery indicators are inaccurate while the batteries are accepting charge. After 8 hours the indicator read 100%, but when disconnected and a cooling cycle was activated the battery level immediately dropped to 75%. This testing procedure is not recommended practice. Charging and preconditioning should be done connected to line power as stated in the operations manual. The battery indicator provides reliable information during discharging. The batteries should be charged for at least 12 hours to ensure a complete charge.

4.5. Post-Test Thermocouple Calibration Check

A post-test calibration check of all TCs was performed according to WKI-5.4.49- Calibration Check Procedure. All TCs[1] used in the data analysis registered within ±0.5°C of reference values. Thermocouples were checked for calibration at -10°C, 10°C and +30°C. The results were recorded in LAB-FORM-0001-04, Temperature Logger Calibration Check Form, which can be seen in Appendix 6.

1. TC-10, coded as TC 15-2 was damaged post-test, registering "open" and could not be checked. TC-12, coded as TC15-1 was in the same location as the failed TC.

5. RESULTS AND DISCUSSION

5.1. Results and Discussion Autonomous Operation (Hot)

The Cold Box demonstrated the capability to maintain all points within 3°C of set point throughout the payload volume for 103 hours. The graphs below show the thermal response. The supply air temperatures ranged from 7.8°C to 1.9°C. The 1.9°C low temperature occurred for one 10 minute data point at the air supply. All other points measured within ±3°C of the 5°C set point. The average temperature of all points measured exterior to the corrugated boxes was 5.3°C with at STD of 0.85°C. Dead band settings greater than 1°C conserve battery power and extend autonomous operation, but may result in wider temperature ranges, especially at the cold air supply location.

Figure 3 Autonomous Operation Test – Hot Profile - Frame Supply and Return Air

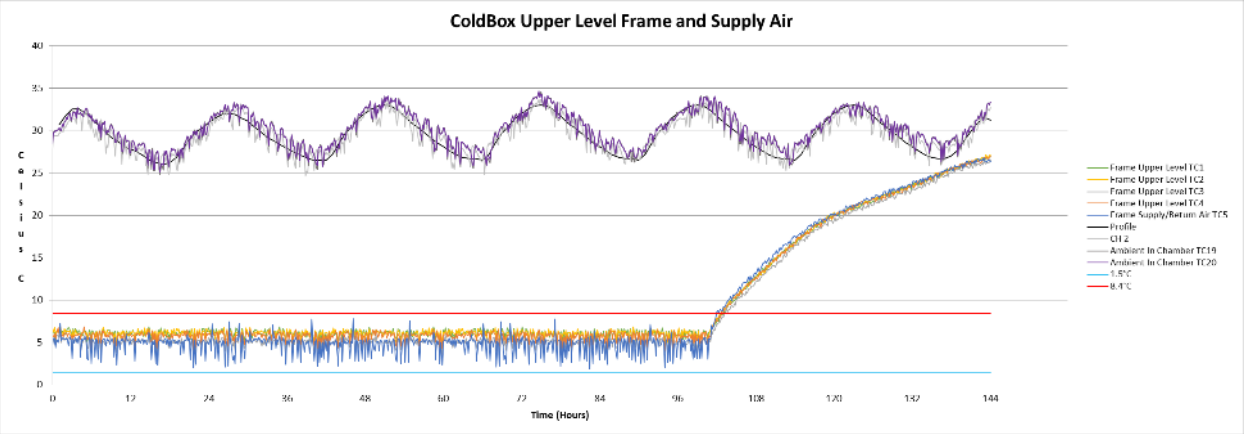


Figure 4 Autonomous Operation Test – Hot Profile - Lower Level Frame and Return Air

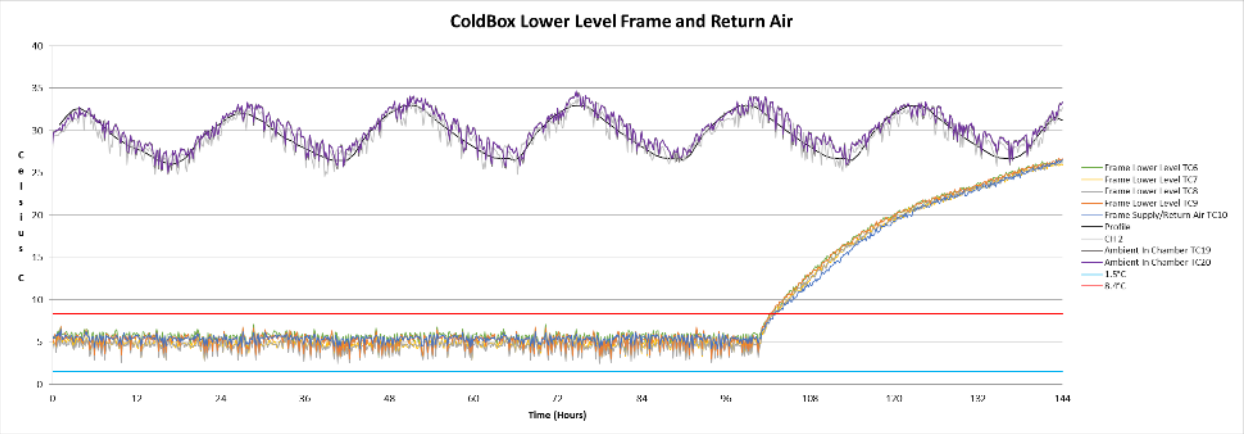


Figure 5 Autonomous Operation Test – Hot Profile - Upper Level Corrugated Boxes

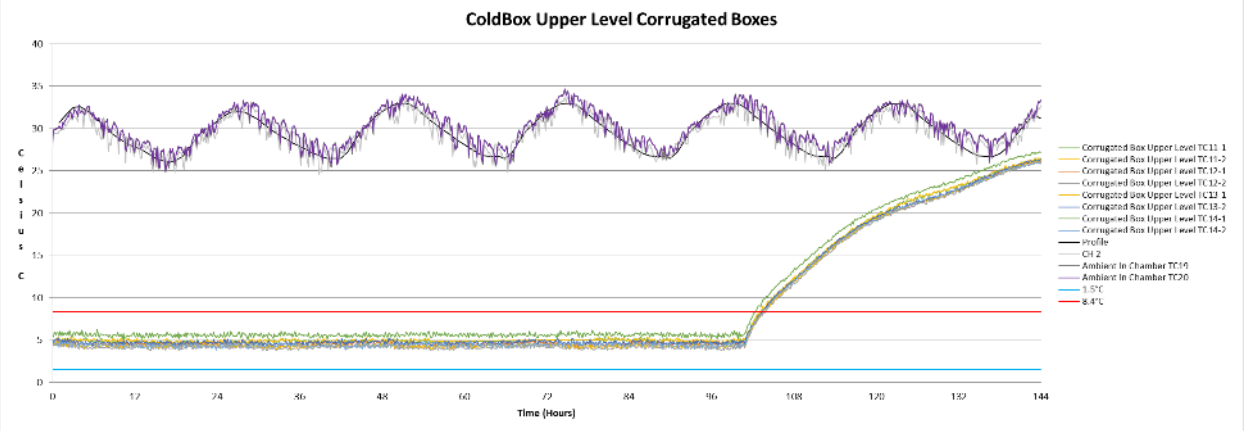
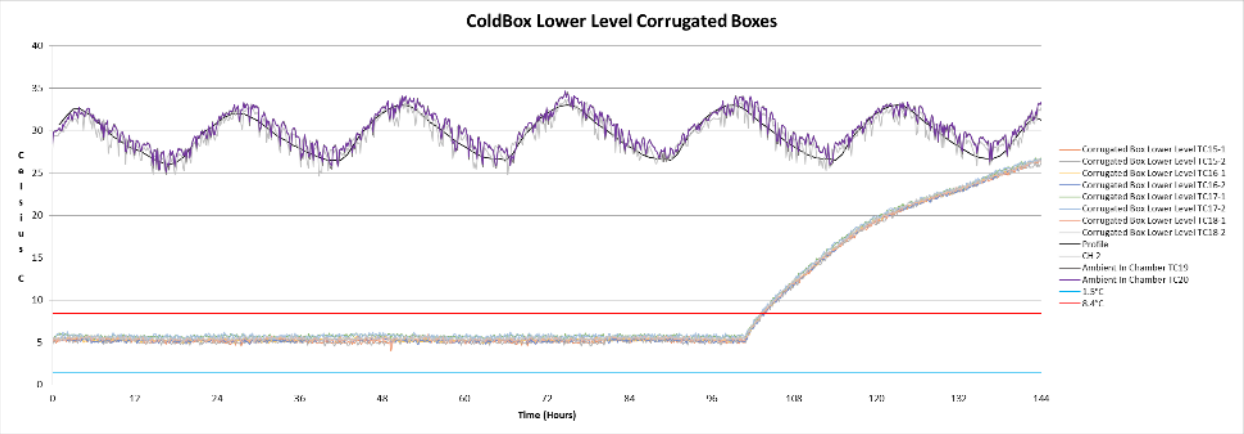


Figure 6 Autonomous Operation Test – Hot Profile - Lower Level Corrugated Boxes



5.2. Results and Discussion Autonomous Operation (Cold)

The Cold Box demonstrated the capability to maintain all points within 3°C of set point throughout the payload volume for 164 hours. There was a chamber error between hours 121 and 141. This error occurred after the end of the five-day test, approximately between the hours of 121 and 140. The battery level was over 50% when the chamber was stopped and the test was ended at 164 hours. With a dead band setting of 1°C, the supply temperatures ranged from 7.2°C to 1.2°C. The 1.2C low temp occurred for one 10 minute data point, all other values were 2°C or above. All other points measured within ±2.8°C of the 5°C set point. The average temperature of all points measured exterior to the corrugated boxes was 5.2°C with at STD of 0.36°C.

Figure 7 Autonomous Operation Test – Cold Profile - Upper Level Frame

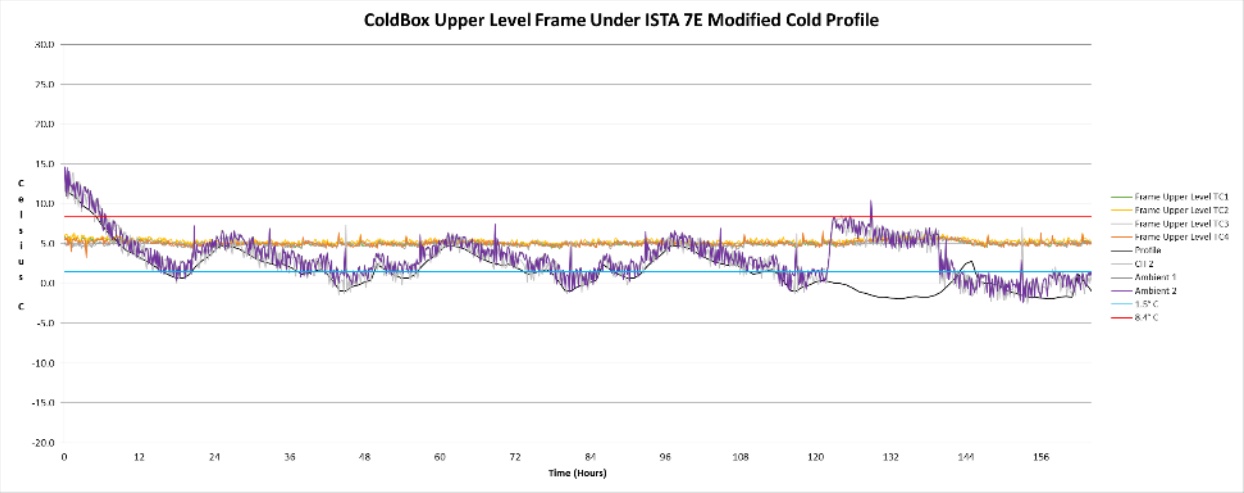


Figure 8 Autonomous Operation Test – Cold Profile - Lower Level Frame

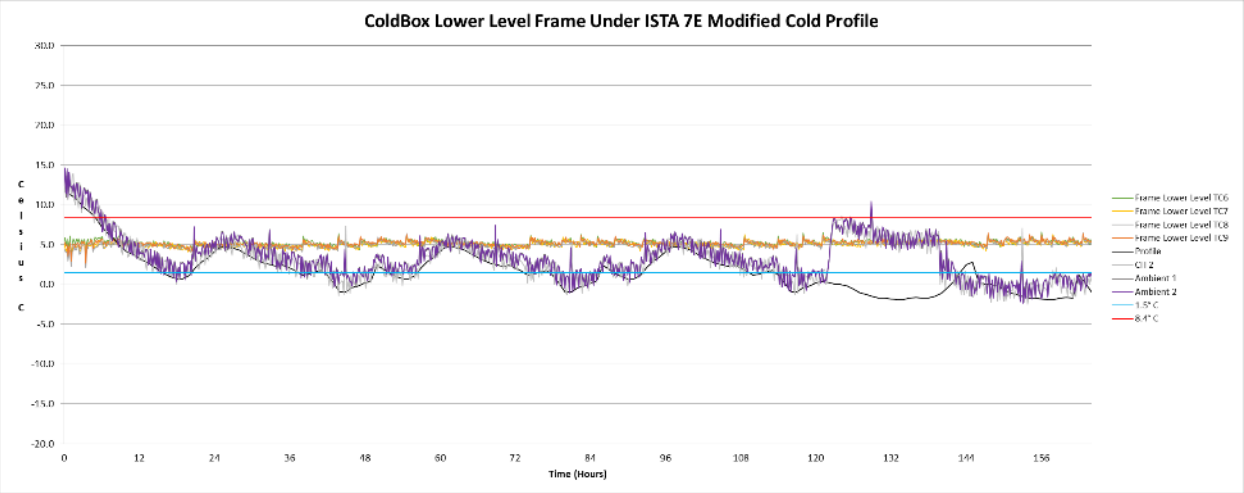


Figure 9 Autonomous Operation Test – Cold Profile - Upper Level Corrugated Boxes

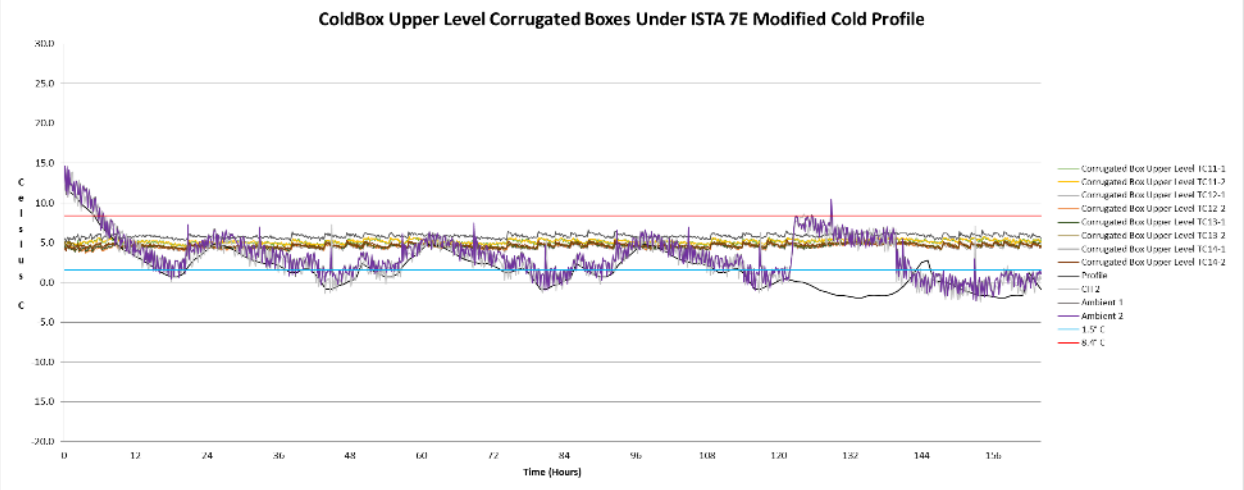


Figure 10 Autonomous Operation Test – Cold Profile - Lower Level Corrugated Boxes

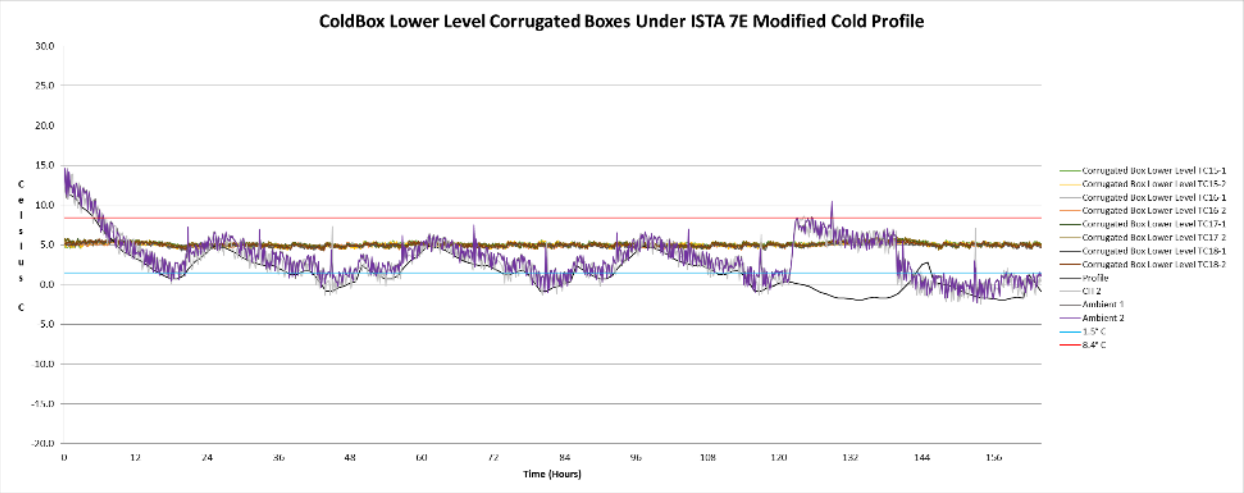
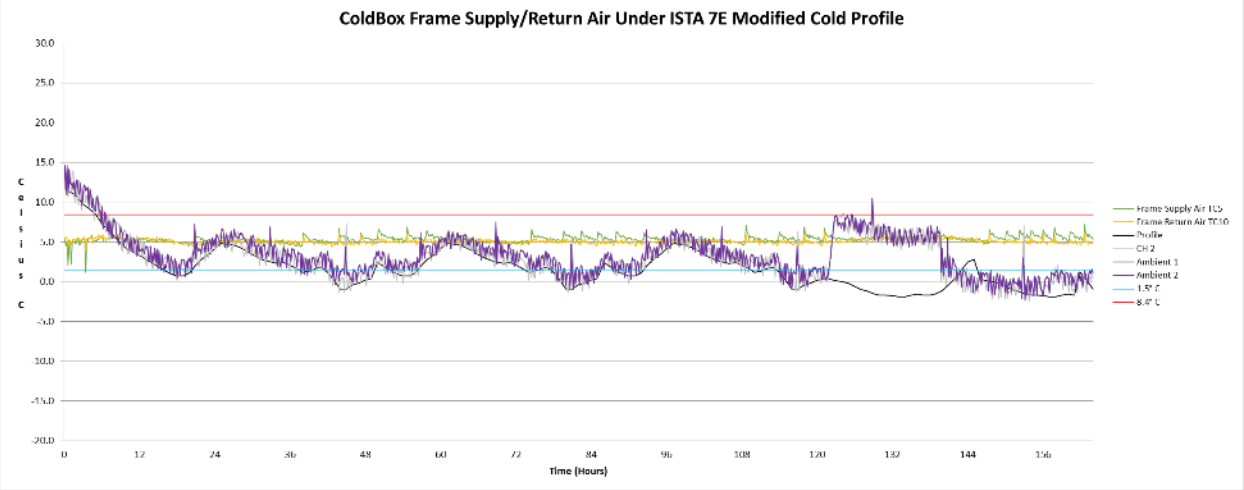


Figure 11 Autonomous Operation Test – Cold Profile – Frame Supply and Return Air



5.3. Results and Discussion: Limit Test (Hot)

With a fully charged battery and while connected to external power, the set point of the Cold Box set to -20°C and was then subjected to a series of hot exposures in order to determine the capability to maintain set point temperatures. All points within the Cold Box were within 5°C of the set point with a bias towards -15°C. As the chamber temperature was raised to 55°C, internal temperatures within the Cold Box trended high. The testing was stopped after the chamber reached 60°C and the last (highest) reading inside the Cold Box was -3°C.

Figure 12 Limit Test – Hot Profile - Upper Level Frame

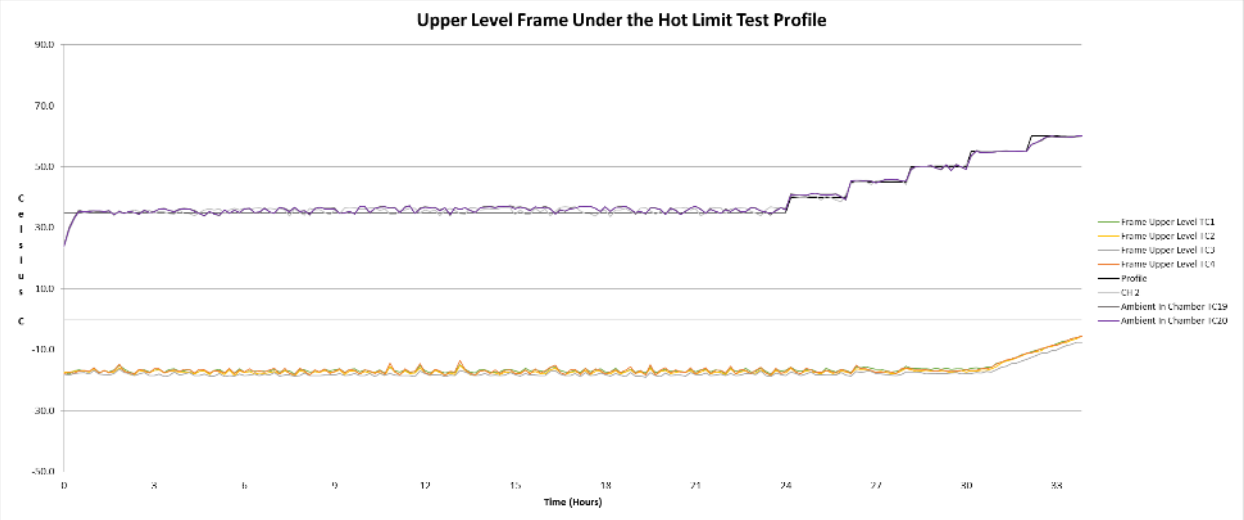


Figure 13 Limit Test – Hot Profile - Lower Level Frame

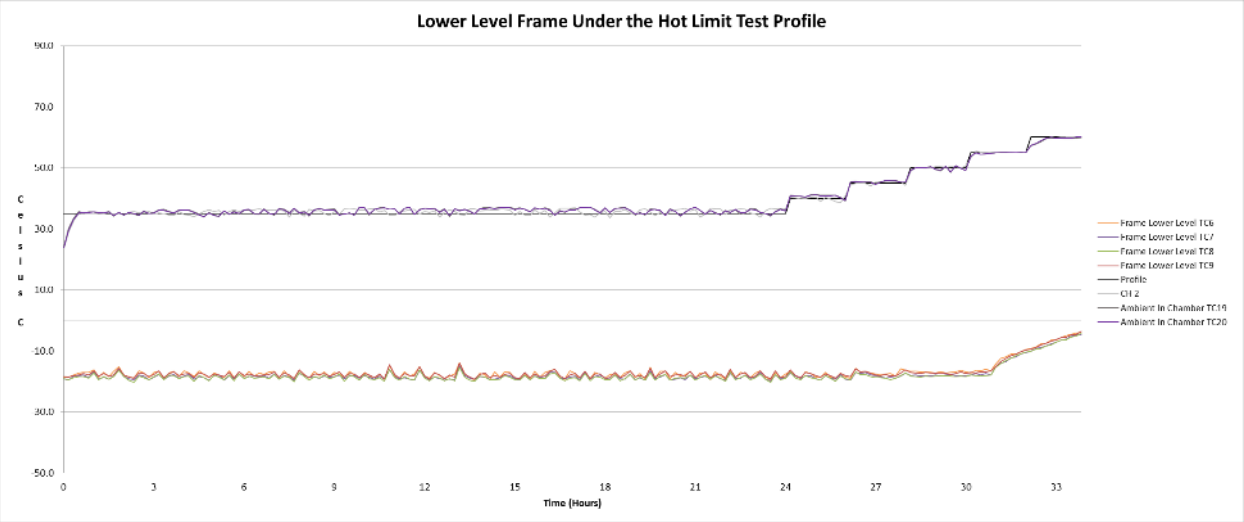


Figure 14 Limit Test – Hot Profile – Frame Supply and Return Air

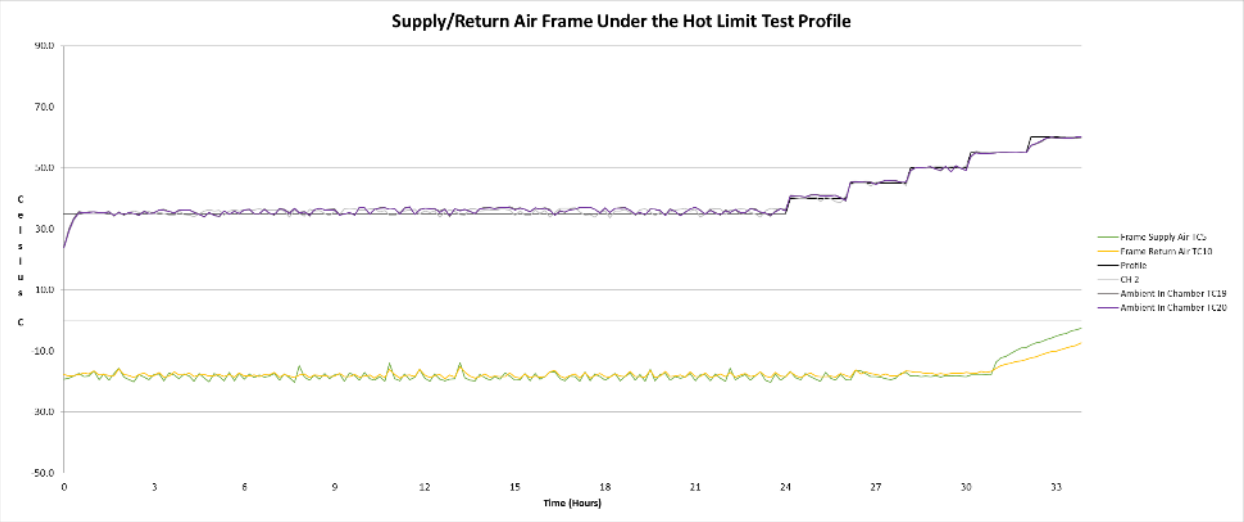


Figure 15 Limit Test – Hot Profile - Upper Level Corrugated Boxes

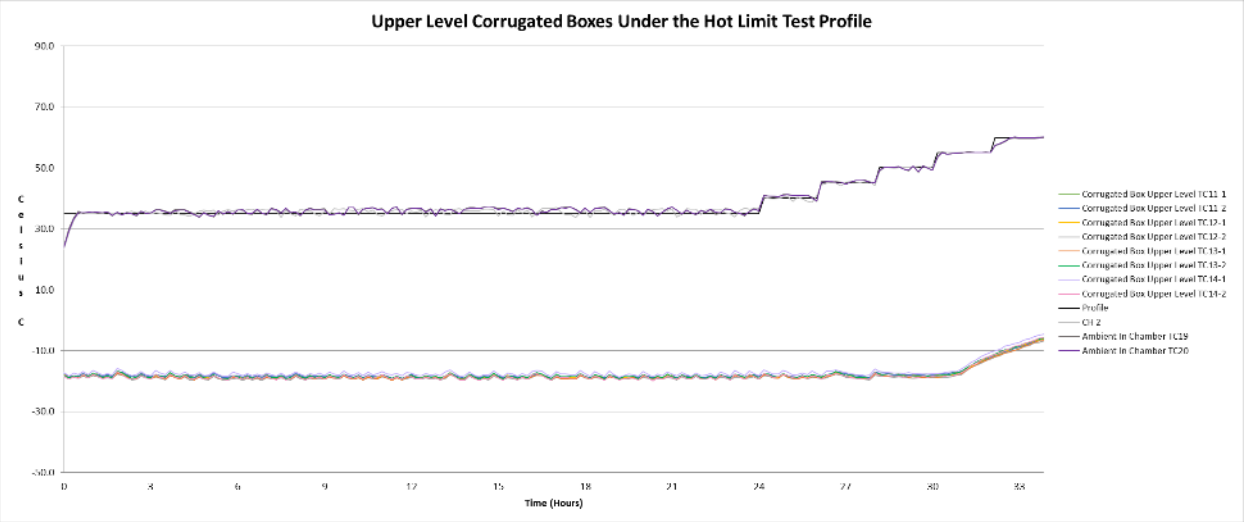
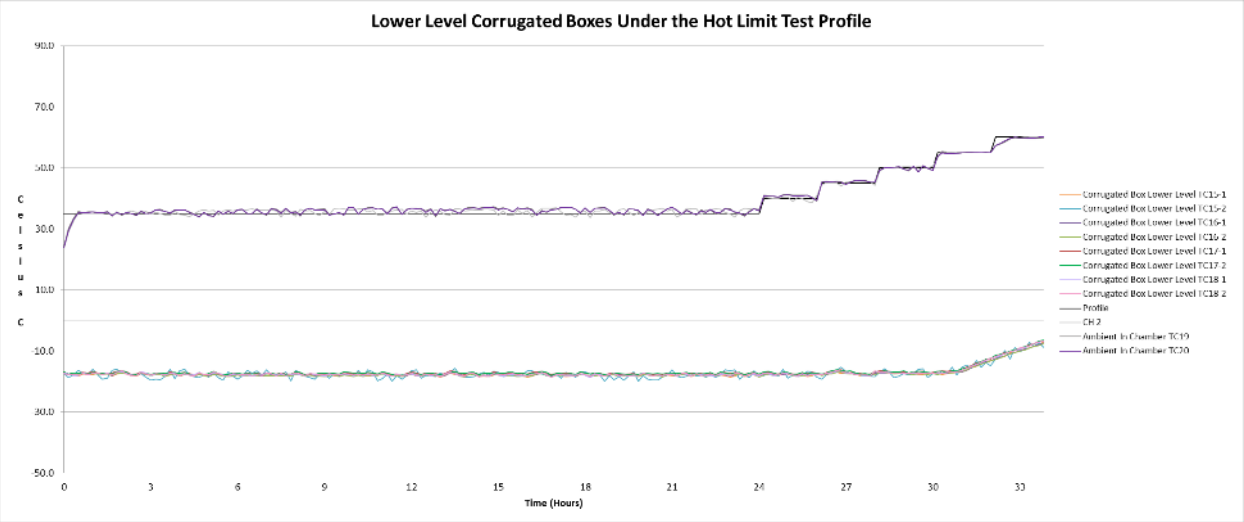


Figure 16 Limit Test – Hot Profile - Lower Level Corrugated Boxes



5.4. Results and Discussion: Limit Test (Cold)

With a fully charged battery and while connected to external power, the set point of the Cold Box was set to +20°C and was then subjected to a series of cold exposures in order to determine the capability to maintain set point temperatures. All points within the Cold Box were within 2.5°C of setpoint with no bias. The Cold Box maintained temperatures during the entire test. The test was stopped at -40°C, which is the lower limit for the chamber.

Figure 17 Limit Test – Cold Profile - Upper Level Frame

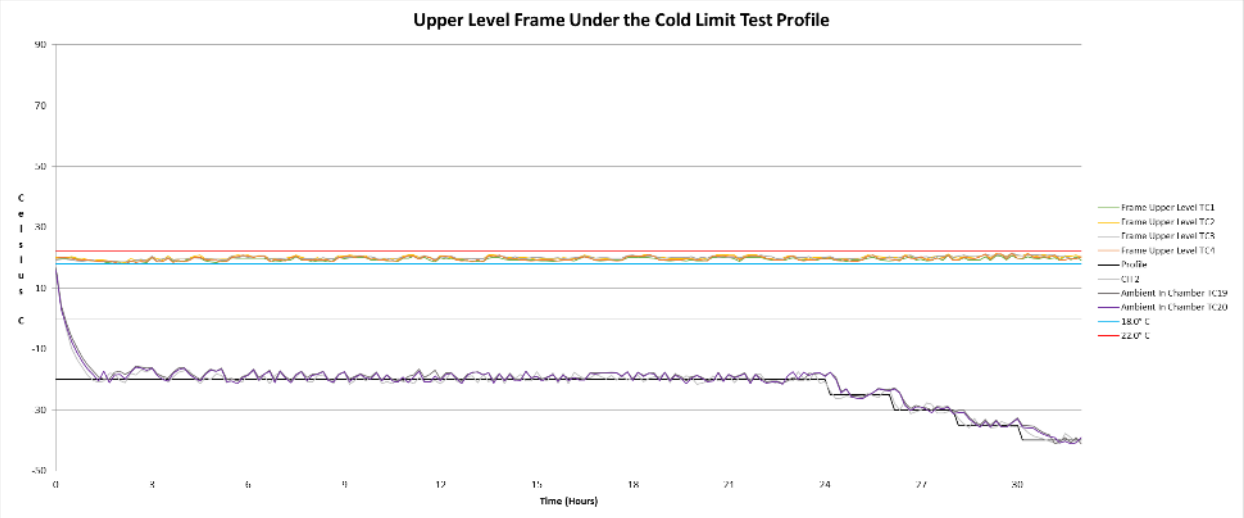


Figure 18 Limit Test – Cold Profile - Lower Level Frame

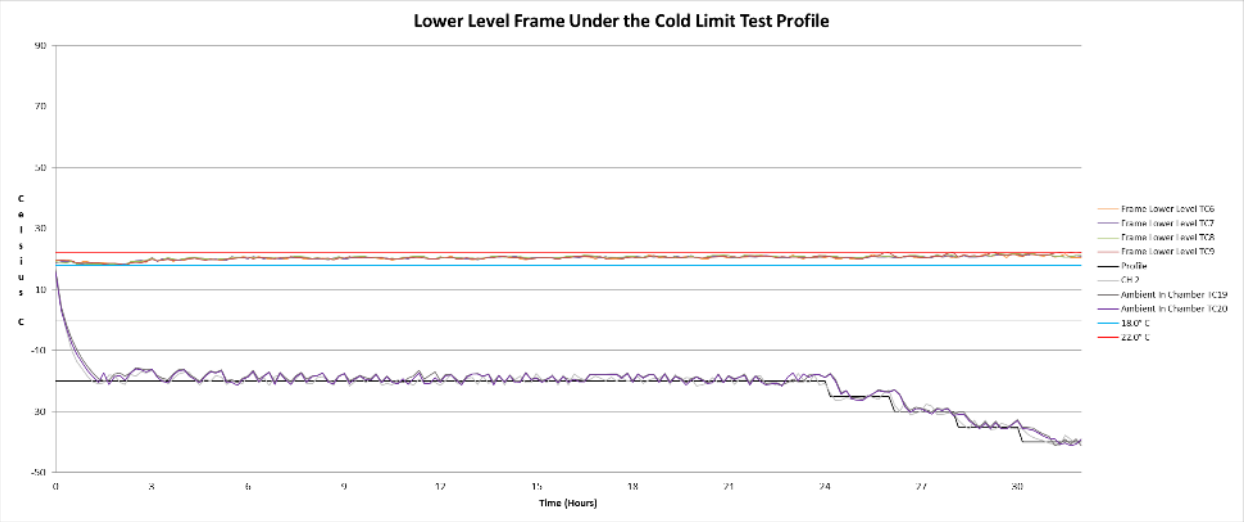


Figure 19 Limit Test – Cold Profile – Supply Air and Return Air Frame

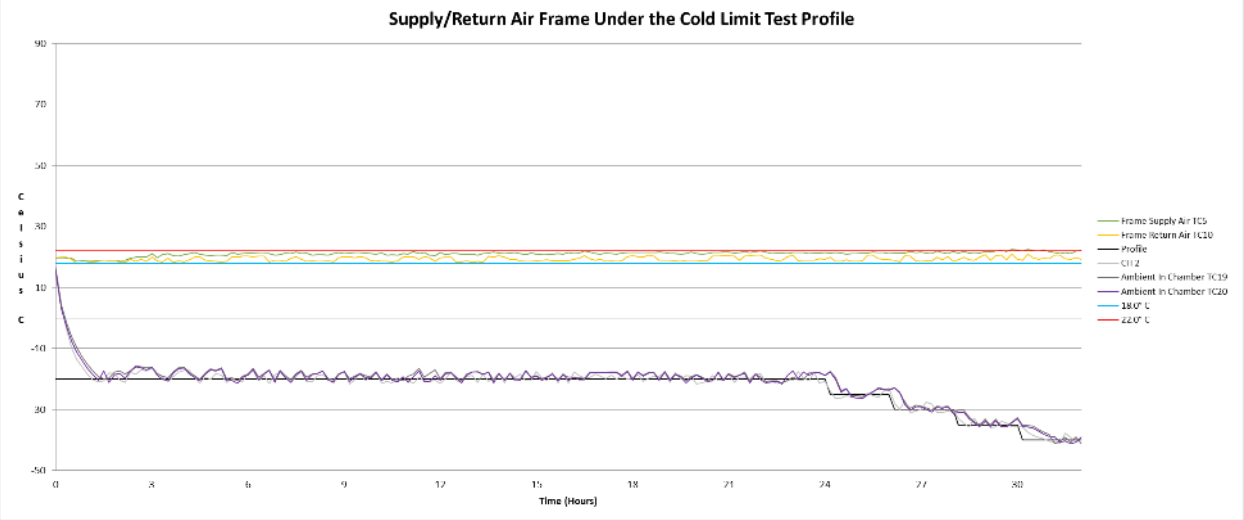


Figure 20 Limit Test – Cold Profile - Upper Level Corrugated Boxes

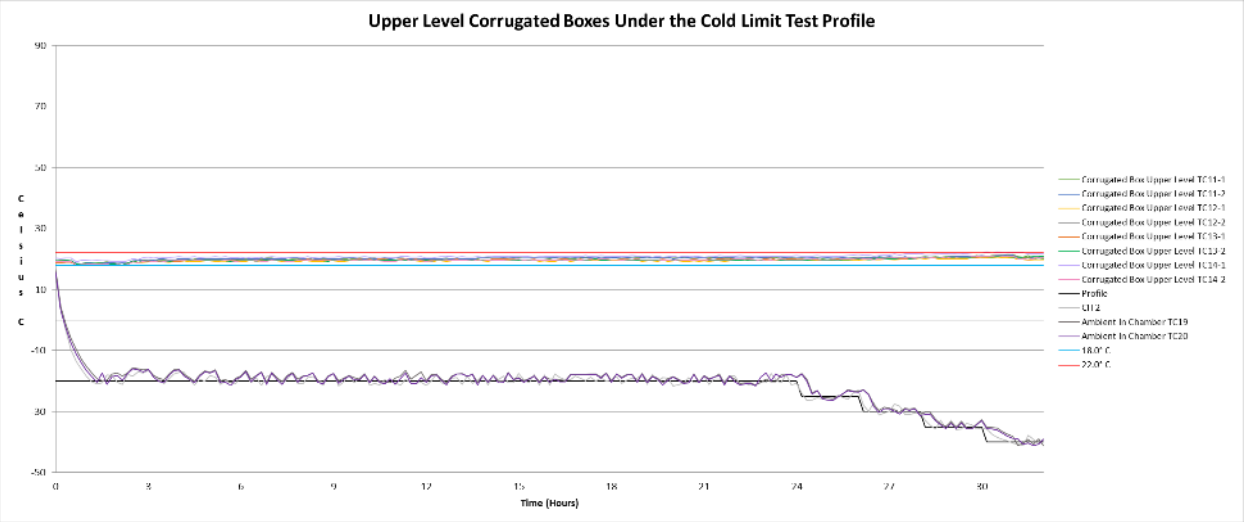
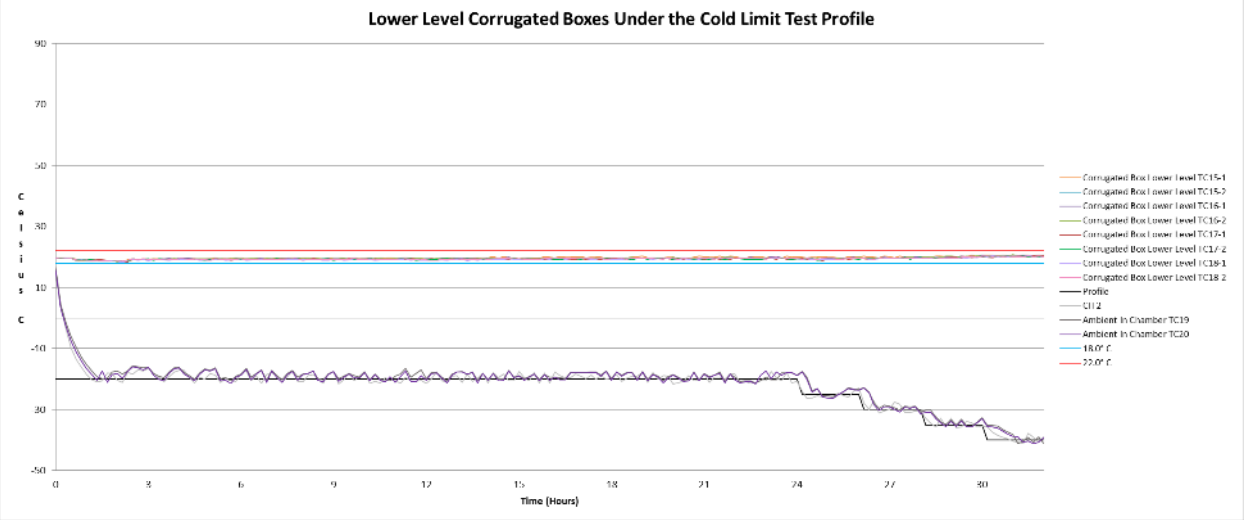


Figure 21 Limit Test – Cold Profile - Lower Level Corrugated Boxes



5.5. Validation Parameters

The validation parameters for this study are presented in Table 7.

Table 7 Validation Parameters

Validation Parameters	PASS/FAIL
Items requiring pre-conditioning were pre-conditioned as per protocol instruction.	PASS
Study conducted according to the steps outlined in this protocol and associated check sheets.	PASS
Preparation and programming of the Cold Box followed all guidance provided in the Cold Box Operations Manual	PASS

5.6. Acceptance Criteria

The acceptance criteria for this study are presented in the Table 8 below.

Table 8 Acceptance Criteria

Test	Acceptance Criteria	PASS/FAIL
Autonomous Testing	Thermal Probes placed inside the corrugated boxes must remain within the refrigerated range, with a one-hour allowance upon starting the test. The time within range will be recorded and define the autonomous operation period.	PASS
Limit Testing	The thermal Probes placed inside the corrugated boxes must remain within of the set point. Is is expected that at some point, as temperature extremes are raised/lowered, the Cold Box will be unable maintain internal temperatures. This ambient point of failure will be recorded.	PASS
Battery Testing	The battery must reach full charge within 8 hours. The only proof of a fully charged battery will be the performance of the following autonomous test.	FAIL*
Laboratory Equipment used must be in current calibration.		PASS
TCs must demonstrate an accuracy of ±0.5°C, measured pre and post-test.		PASS**

* Battery must be charged for a full 12-hour period.

** TC10 was damaged post-test. Backup TC reported all data.

5.7. Protocol Deviations

TC-10, coded as TC 15-2 was damaged post-test, registering “open” and could not be checked. TC-12, coded as TC15-1 was in the same location as the failed TC. No impact to study.

6. APPENDICES

The appendices included in this study are presented in Table 9.

Table 9 Appendices

Appendix	Title
Appendix 1	Cold Box Specification
Appendix 2	Protocol OQ- Q040215S2: Cold Box Studies; Box 111412
Appendix 3	Calibration Certificates
Appendix 4	Pre-test Thermocouple Calibration Form
Appendix 5a	Protocol Checklist associated with Autonomous Operation Test
Appendix 5b	Protocol Checklist associated with Limit Testing
Appendix 6	Post-test Thermocouple Calibration Form
Appendix 7	Data Package

7. REFERENCES

IQ/OQ PROTOCOL COLD BOX EXPRESS

COLD BOX OPERATIONS MANUAL

DOCUMENT HISTORY

VERSION 1-APPROVED ON 25JUN2015

VERSION 2- ISSUED ON 2JUL2015

A. CORRECTED TYPOS

B. ADDED AVERAGE AND STANDARD DEVIATION CALCULATIONS FOR AUTONOMOUS TESTS

C. ADDED DETAIL ABOUT TC “OPEN” ON TC#10, CODED AS TC15-2 IN DATA PACKAGE.