

Customer: FedEx Corporation  
Document Type: Qualification Report  
Product: 2-153853A  
Document Date: 27 April 2016  
Document Number: CQR-002-16 rev. 00

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# Qualification Report For the NanoCool Long Haul Shipping System 2-153853A

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## Purpose

This report outlines testing for the qualification of the 2-153853A NanoCool Long Haul shipping system. The 2-153853A systems were tested in triplicate against ten different ambient profiles for durations of up to one week. Three 2-153853A systems were drop tested against a modified ISTA-3A drop procedure.

## Summary

An extended duration system has been developed for nominal 2 to 8 °C shipments with durations (depending upon the ambient temperatures) of four to seven days. As with all NanoCool systems, this system is designed to start at ambient temperature with no preconditioning.

As shipment durations increase in length because of either international shipping with the possibility of customs delays or because of a move to ground shipping to lower freight costs, the ambient temperature profile that the NanoCool system will be subjected to becomes more uncertain. Therefore, we have tested the systems against ten different ambient profiles that are used in a range of geographies. These include:

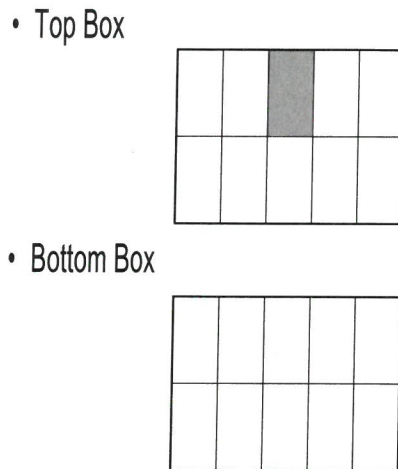
- Modified ISTA-7D 96 hour summer and winter profiles where an additional 24 hour 30 °C (summer) or 10 °C (winter) plateau was added to the 72 hour ISTA-7D profiles
- ISC Silver and Gold summer and winter profiles.
- EU summer high, summer low, winter high and winter low profiles

## Thermal Test Procedures

Testing was conducted using two different configurations of twenty 5 mL vials. For the ISTA-7D summer and winter profiles, two boxes containing 10 horizontal vials each were stacked on top of each other. The vial that was data logged is indicated in gray in the top view illustrated in Figure 1.

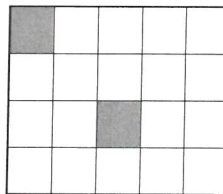
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**Figure 1. horizontal 5 mL vial configuration**



For all other profiles, one box containing 20 vertical vials was employed. The two vials that are data logged are indicated in gray via the top view shown in Figure 2. The corner vial is indicated as P1 and the central logged vial is designated as P3.

**Figure 2. vertical 5 mL vial configuration**



All placebo products contained deionized water. The vials being monitored were probed prior to the vials being preconditioned at 3-5°C.

Prepare for testing:

- Precondition the 5mL vials at 3-5°C for 24 hours
- Prepare TIS (test information sheets), assign logger and chamber
- Prepare NanoCool shipping systems according to TIS sheet
- Obtain appropriate coolers for testing
- Assign coolers to boxes, documenting cooler numbers and box numbers on TIS

When coolers, boxes, products and chambers are prepared, start hook-up procedures.

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## Hook-Up Procedure

- Open box and remove cooler
- Place cooler upside down, dome up, and activate
- Obtain two cartons of vials, one vial in each probed with the thermocouple assigned on the TIS
- Place cartons in the payload cavity
- Place cooler onto the box
- Close outer box
- Place systems in the chamber
- Ensure that boxes are not touching
- Close chamber
- Turn on logger
- Turn on chamber with correct testing profile

## Downloading and Autopsy Procedure

- Download loggers according to download procedures
- Graph experiments according to graphing procedures and information on the test information sheet
- Analyze data to determine minimum and maximum temperatures over 96 hours
- The chamber and loggers used for each test are shown in the Table 1

Table 1. Chamber and logger identification.

Run Number	Profile	Chamber	Logger
WFB2010-#72	96 HR ISTA Summer	ZPO453561	EL-8174
WFB2010-#74	96 HR ISTA Winter	ZPO453562	EL-8110
WFB2010-#88	ISC Silver Summer	ZPO453561	EL-7416
WFB2010-#90	ISC Silver Winter	ZPO453562	EL-8174
WFB2010-#102	ISC Gold Summer	ZPO453561	EL-8174
WFB2010-#100	ISC Gold Winter	ZPO453562	EL-7416
WFB2010-#111	EU Summer High	ZP0553772	EL-8110
WFB2010-#118	EU Summer Low	ZP0553772	EL-8173
WFB2010-#116	EU Winter High	ZPO453562	EL-7416
WFB2010-#120	EU Winter Low	ZPO453562	EL-8173



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## Drop Test Procedures

The purpose of this test is to evaluate the durability of the 2-153853A NanoCool shipping system. Three 2-153853A NanoCool shipping systems were drop tested against the ISTA-3A protocol (see Table 2) with the addition of two 60" face one drops during the procedure. The two 60" drops on face one are to test the integrity of the NanoCool shipping system's engine. After the completion of the ISTA test sequence, the NanoCool shipping system is opened and inspected to see if it passes the acceptance criteria (see page 6). If the system passes the acceptance criteria guidelines the units are inspected again after twenty-four hours.

**Table 2: Drop Sequence**

ISTA 3A Drop Sequence		
Drop #	Drop Height (in)	Orientation
1	18"	Edge 3-4
2	18"	Edge 3-6
3	18"	Edge 4-6
4	18"	Corner 3-4-6
5	18"	Corner 2-3-5
6	18"	Edge 2-3
7	18"	Edge 1-2
8	36"	Face 3
9	18"	Face 3
10	60"	Face 1 on Hazard
11	18"	Edge 3-4
12	18"	Edge 3-6
13	18"	Edge 1-5
14	18"	Corner 3-4-6
15	18"	Corner 1-2-6
16	18"	Corner 1-4-5
17	36"	Face 1
18	60"	Face 1

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## Set-up

Each unit will be assembled in the following manner prior to the initiation of ISTA-3A.

- Obtain correct systems
- Ensure package component integrity prior to testing
- Remove cooler and activate if specified
- Replace cooler engine
- Close NanoCool shipping unit
- Using packing-style adhesive tape, seal the shipping units in the manner indicated by the shipping unit graphics, sealing face 2 to face 5, face 2 to face 6, and face 2 to face 3
- Number outer shipping box according to ISTA-3A drop testing procedures
- Establish 18", 36" and 60" drop testing height

## Inspection and Acceptance Criteria

Visually inspect the NanoCool shipping systems for the following:

- Rips in the corrugate shipping case material
- Adhesion of the foam pad to the inside of Face 1
- Cooler engine integrity
  - Burst bladder
  - Loss of vacuum
- Integrity of the vacuum insulation panel (VIP)
  - Loss of vacuum
  - Structure maintained

Failure: loss of cooler or VIP integrity as listed above.  
Document all other observations related to above criteria.

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## Summary of Results

### ISTA-7D 96 Hour Summer Profile

Test WFB2010-#72 tested three 2-153853A NanoCool shipping systems against the modified ISTA-7D summer 96 hour profile (Figure 3). Two cartons of 5mL vials, each holding ten vials, were used as a placebo product. The product temperature stayed within a range of 2 and 8° for between 93 and 108 hours.

Figure 3: ISTA-7D Summer

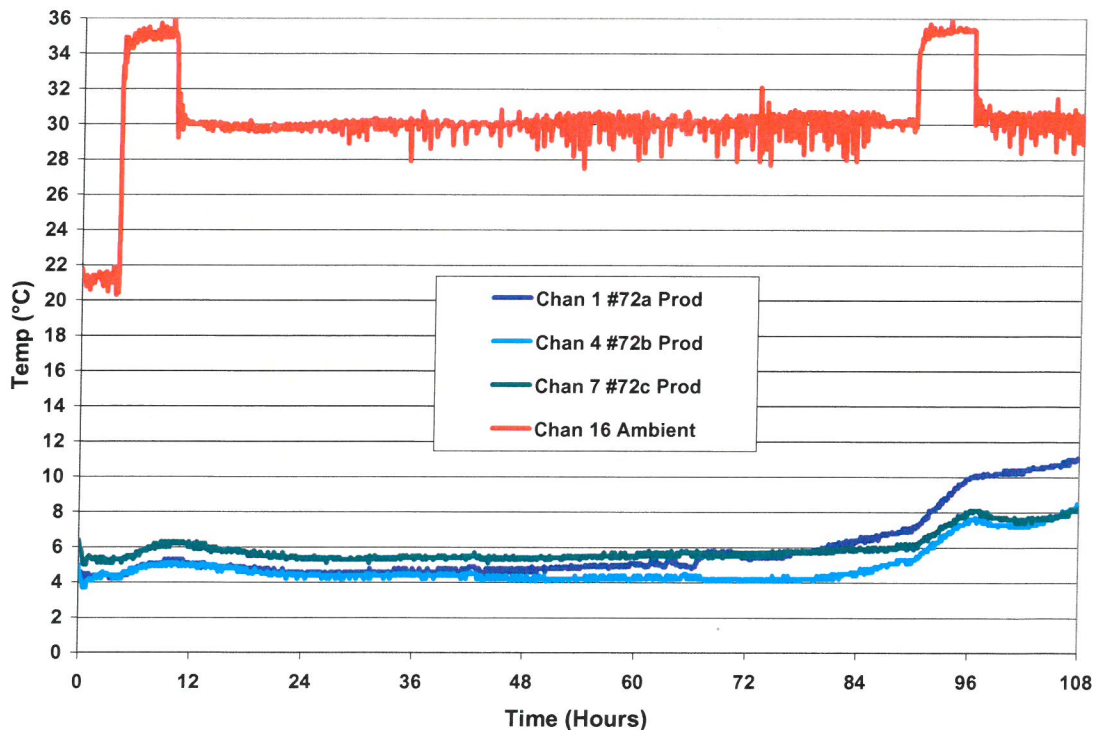


Table 3. Minimum and maximum temperature for the first 96 hours of test

	72a	72b	72c
Minimum Temperature	4.1	3.7	5.0
Maximum Temperature	9.9	7.6	8.0

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### ISTA-7D 96 Hour Winter Profile

Test WFB2010-#74 tested three 2-153853A NanoCool shipping systems against the ISTA-7D winter 96 hour profile (see Figure 4). Two cartons of 5mL vials, each carton holding ten vials, were used as a placebo product. All three systems performed identically and maintained product temperatures between 2-8°C for approximately 92 hours of the test.

Figure 4. ISTA-7D Winter profile

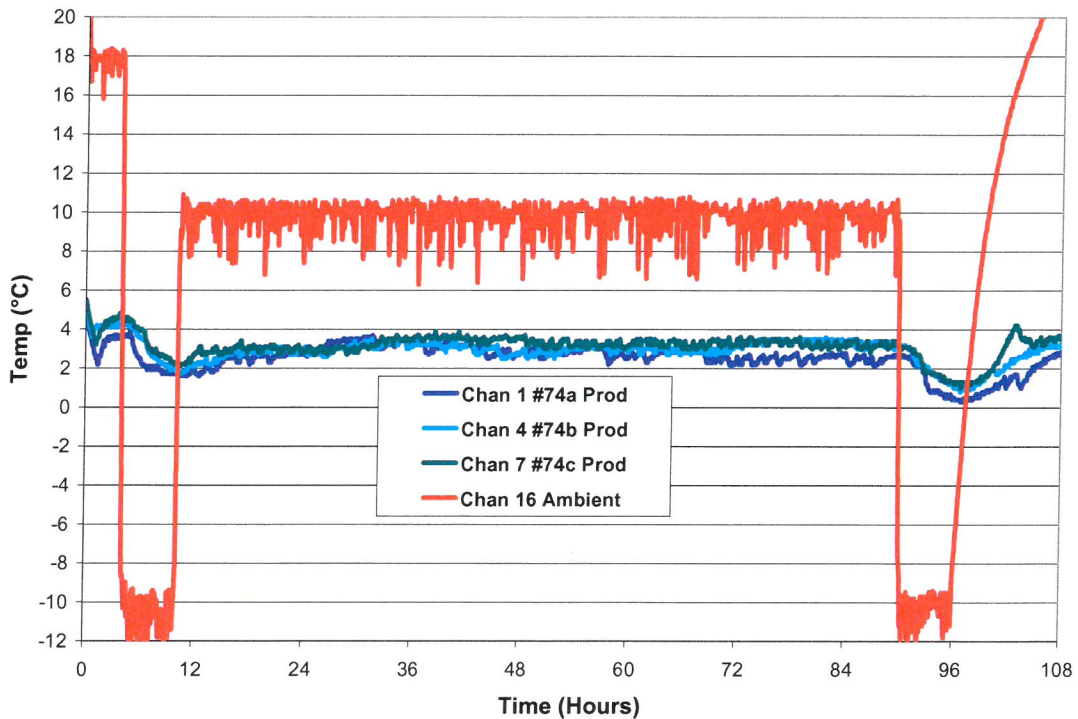


Table 4. Minimum and maximum temperature for the first 96 hours of test

	74a	74b	74c
<b>Minimum Temperature</b>	<b>0.9</b>	<b>0.9</b>	<b>1.0</b>
<b>Maximum Temperature</b>	<b>6.8</b>	<b>6.7</b>	<b>6.9</b>



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### ISC Silver Summer Profile

Test WFB2010-#88 tested three 2-153853A NanoCool shipping systems against the ISC Silver Summer profile which was repeated for the 168 hours of the test (see Figure 5). One carton of 20 5mL vials was used as a placebo product. Two vial locations, which should have the largest spread of temperature, were logged for each system. All three systems performed identically and maintained product temperatures between 2-8°C for approximately 116 and 123 hours.

Figure 5. ISC Silver Summer Profile

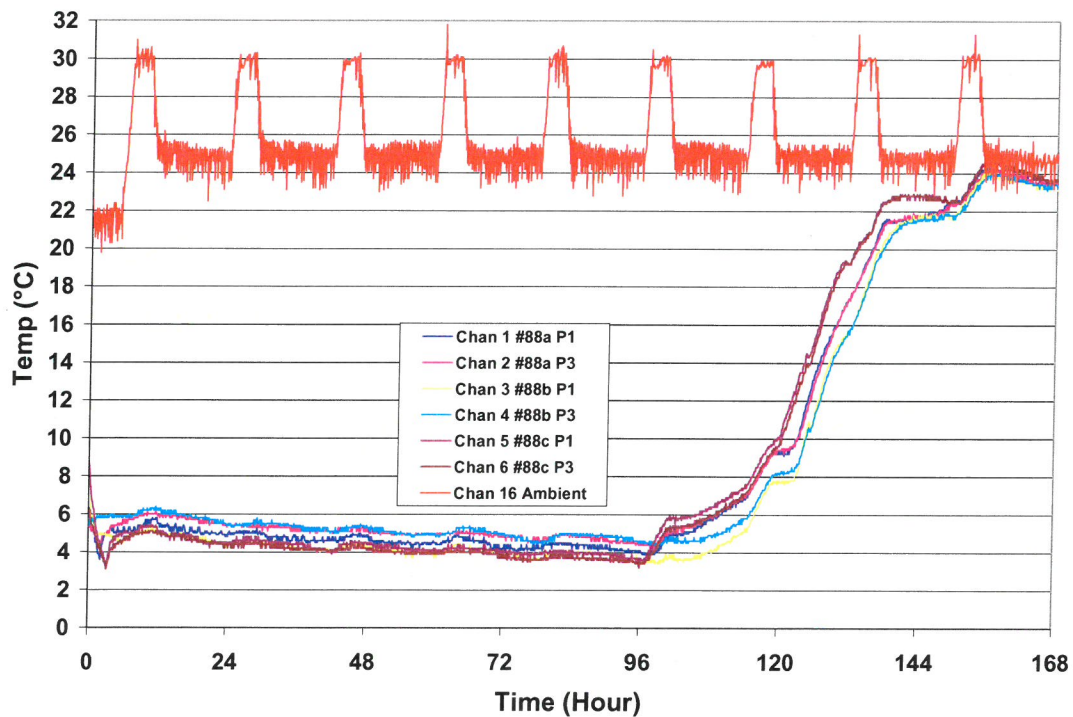


Table 5. Minimum and maximum temperature for the first 96 hours of test

	88a P1	88a P3	88b P1	88b P3	88c P1	88c P3
Minimum Temperature	3.6	4.4	3.6	4.4	3.4	3.1
Maximum Temperature	6.6	6.2	6.7	6.4	8.5	6.3

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## ISC Silver Winter Profile

Test WFB2010-#90 tested three 2-153853A NanoCool shipping systems against the ISC Silver Winter profile which was repeated for the 168 hours of the test (see Figure 6). One carton of 20 5mL vials was used as a placebo product. Two vial locations, which should have the largest spread of temperature, were logged for each system. All three systems performed identically and maintained product temperatures between 2-8°C for approximately 163 hours of the test.

Figure 6. ISC Silver Winter Profile

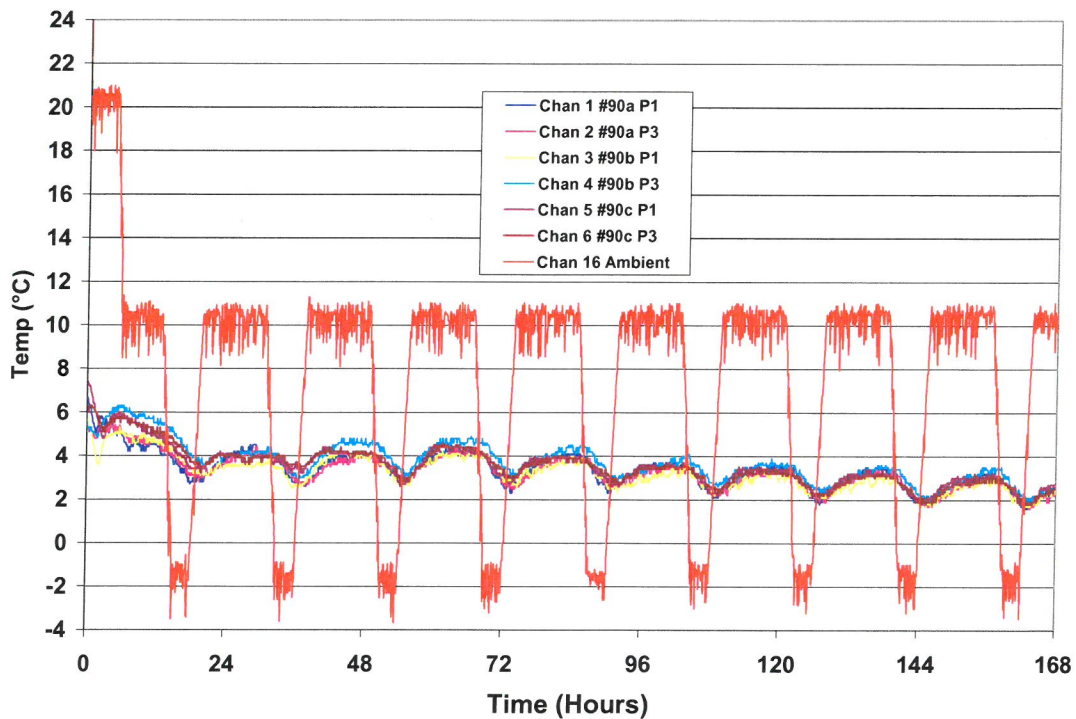


Table 6. Minimum and maximum temperature for the first 96 hours of test

	90a P1	90a P3	90b P1	90b P3	90c P1	90c P3
<b>Minimum Temperature</b>	2.3	2.5	2.3	2.8	2.6	2.7
<b>Maximum Temperature</b>	6.7	5.5	5.9	6.3	7.4	6.3

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## ISC Gold Summer Profile

Test WFB2010-#102 tested three 2-153853A NanoCool shipping systems against the ISC Gold Summer profile which was repeated for the 168 hours of the test (see Figure 7). One carton of 20 5mL vials was used as a placebo product. Two vial locations, which should have the largest spread of temperature, were logged for each system. Against the extreme continued warmth of this profile (average temperature is 33 °C), these NanoCool systems maintain 2-10 °C product temperatures for approximately 90 hours.

Figure 7. ISC Gold Summer Profile

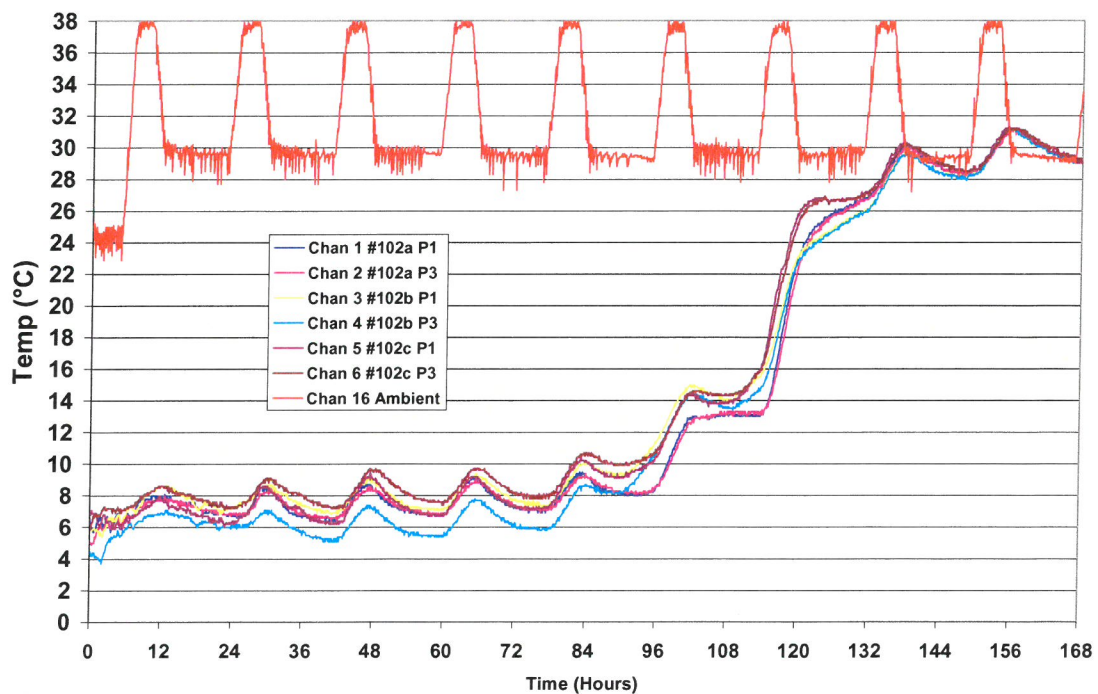


Table 7. Minimum and maximum temperature for the first 96 hours of test

	102a P1	102a P3	102b P1	102b P3	102c P1	102c P3
Minimum Temperature	5.7	4.9	5.4	3.7	5.9	5.9
Maximum Temperature	9.5	9.4	11.4	10.7	10.5	10.9



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### ISC Gold Winter Profile

Test WFB2010-#100 tested three 2-153853A NanoCool shipping systems against the ISC Gold Winter profile which was repeated for the 168 hours of the test (see Figure 8). One carton of 20 5mL vials was used as a placebo product. Two vial locations, which should have the largest spread of temperature, were logged for each system. Against the extreme continued cold of this profile (average temperature is ~0 °C), these NanoCool systems stay above 2 °C for approximately 48 hours. In addition, for some systems, the water in the NanoCool system freezes which temporarily retards its' cooling capacity and causes minor warm deviations for two systems.

Figure 8. ISC Gold Winter Profile

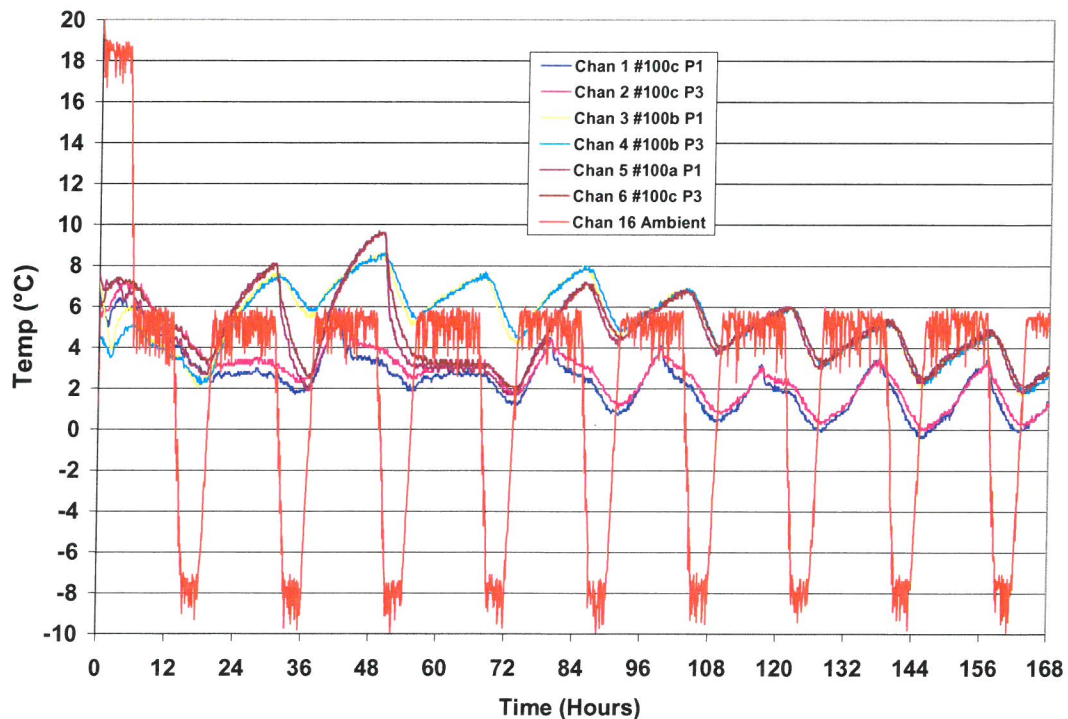


Table 8. Minimum and maximum temperature for the first 96 hours of test

	100a P1	100a P3	100b P1	100b P3	100c P1	100c P3
Minimum Temperature	0.7	1.0	2.1	2.2	1.7	1.9
Maximum Temperature	6.7	7.2	8.6	8.6	9.7	9.6



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## EU Summer High Profile

Test WFB2010-#111 tested three 2-153853A NanoCool shipping systems against EU summer high profile which was repeated for the 168 hours of the test (see Figure 9). One carton of 20 5mL vials was used as a placebo product. Two vial locations, which should have the largest spread of temperature, were logged for each system. Despite this being the EU summer high profile, product stayed in the range of 2 to 8 °C for between 122 and 160 hours.

Figure 9. EU Summer High Profile

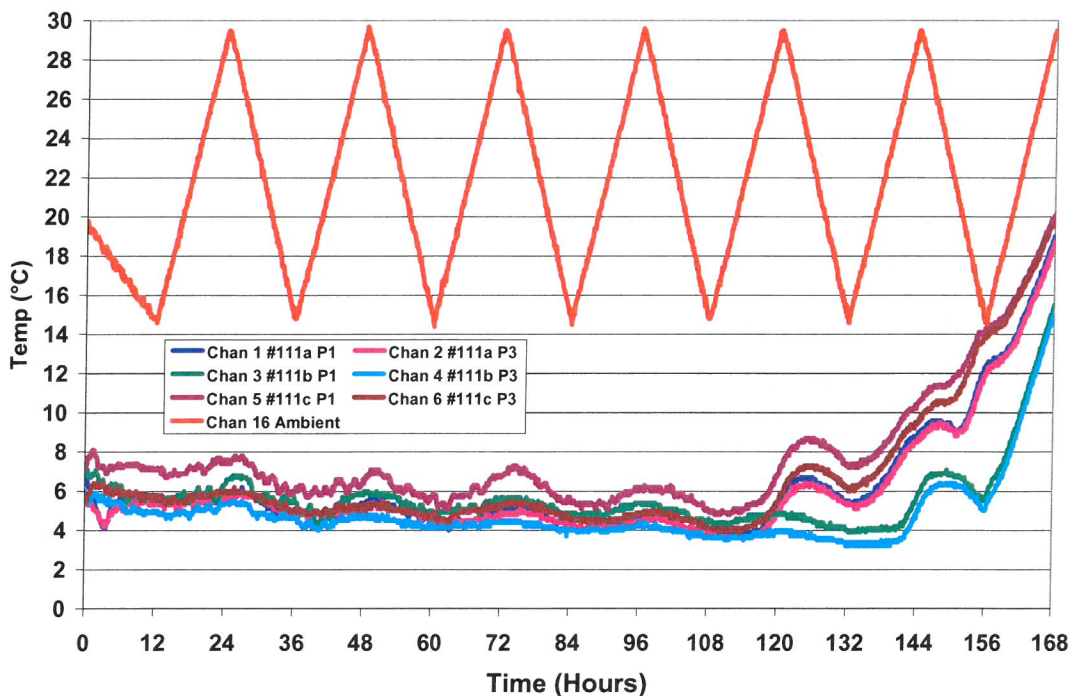


Table 9. Minimum and maximum temperature for the first 96 hours of test

	111a P1	111a P3	111b P1	111b P3	111c P1	111c P3
Minimum Temperature	3.9	4.0	4.2	3.7	5.7	4.4
Maximum Temperature	6.6	6.0	7.1	6.0	8.1	6.4

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## EU Summer Low Profile

Test WFB2010-#118 tested three 2-153853A NanoCool shipping systems against the EU summer low profile which was repeated for the 168 hours of the test (see Figure 10). One carton of 20 5mL vials was used as a placebo product. Two vial locations, which should have the largest spread of temperature, were logged for each system. The product stayed in the range of 2 to 8 °C for the entire 168 hours of the test. The exception is the very short time result for 118a/P1 for which the product was left at room temperature for too long after being taken from the conditioning refrigerator and started the test warmer than 8 °C. In less than 1 hour, that vial was cooled to less than 8 °C.

Figure 10. EU Summer Low Profile

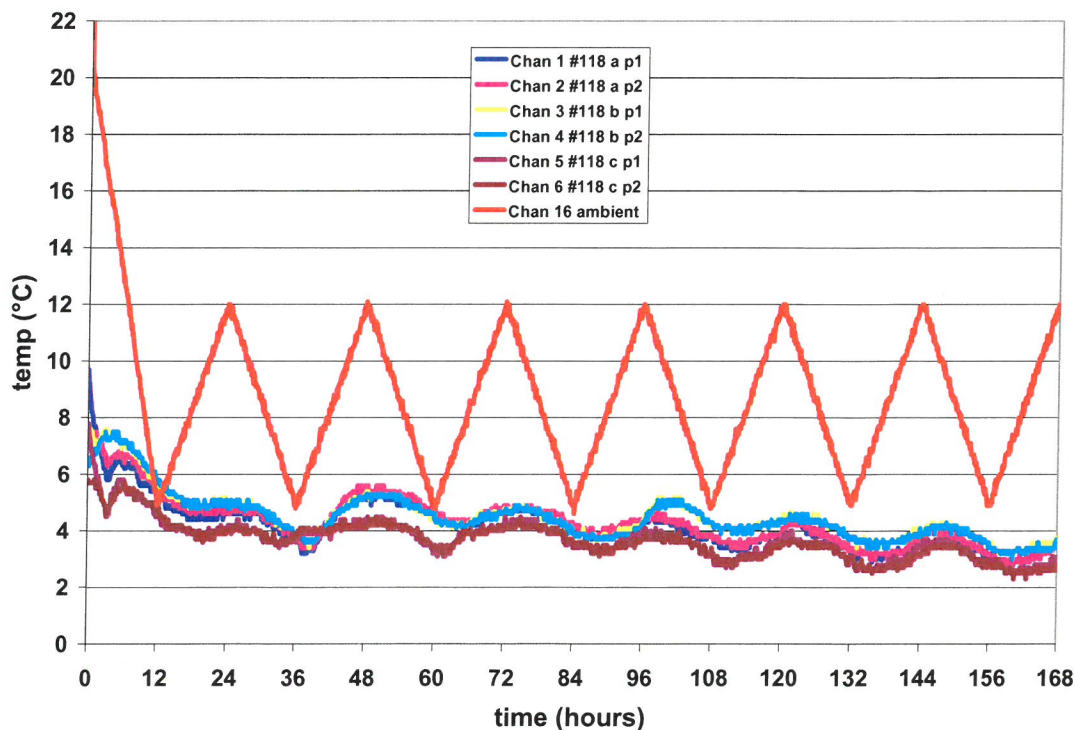


Table 10. Minimum and maximum temperature for the first 96 hours of test

	118a P1	118a P3	118b P1	118b P3	118c P1	118c P3
Minimum Temperature	3.2	3.4	3.4	3.6	3.1	3.1
Maximum Temperature	9.3	7.5	7.7	7.5	7.7	5.8

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## EU Winter High Profile

Test WFB2010-#116 tested three 2-153853A NanoCool shipping systems against the EU winter high profile which was repeated for the 168 hours of the test (see Figure 11). One carton of 20 5 mL vials was used as a placebo product. Two vial locations, which should have the largest spread of temperature, were logged for each system. The product stayed in the range of 2 to 8 °C for the entire 168 hours of the test.

Figure 11. EU Winter High Profile

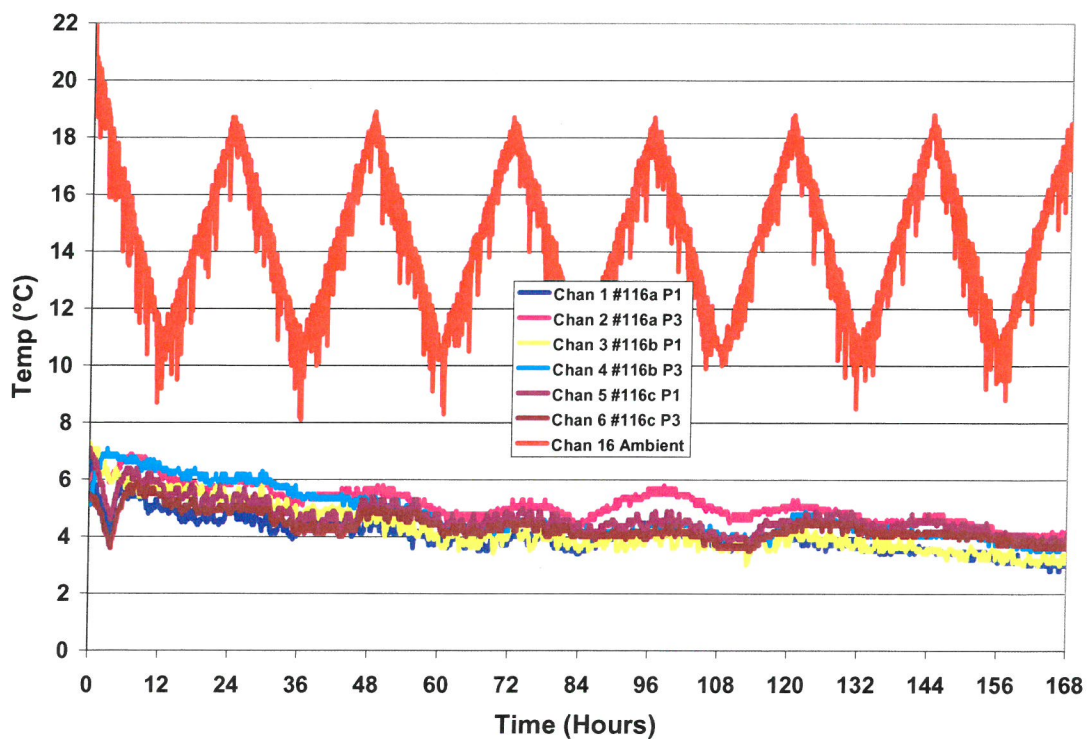


Table 11. Minimum and maximum temperature for the first 96 hours of test

	116a P1	116a P3	116b P1	116b P3	116c P1	116c P3
Minimum Temperature	3.4	4.4	3.4	4.0	4.0	3.6
Maximum Temperature	6.6	6.9	7.1	7.1	7.1	5.9



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## EU Winter Low Profile

Test WFB2010-#120 tested three 2-153853A NanoCool shipping systems against the EU winter low profile which was repeated for the 168 hours of the test (see Figure 12). One carton of 20 5mL vials was used as a placebo product. Two vial locations, which should have the largest spread of temperature, were logged for each system. The product stayed in the range of 1 to 8 °C for the 168 hours of the test.

Figure 12. EU Winter Low Profile

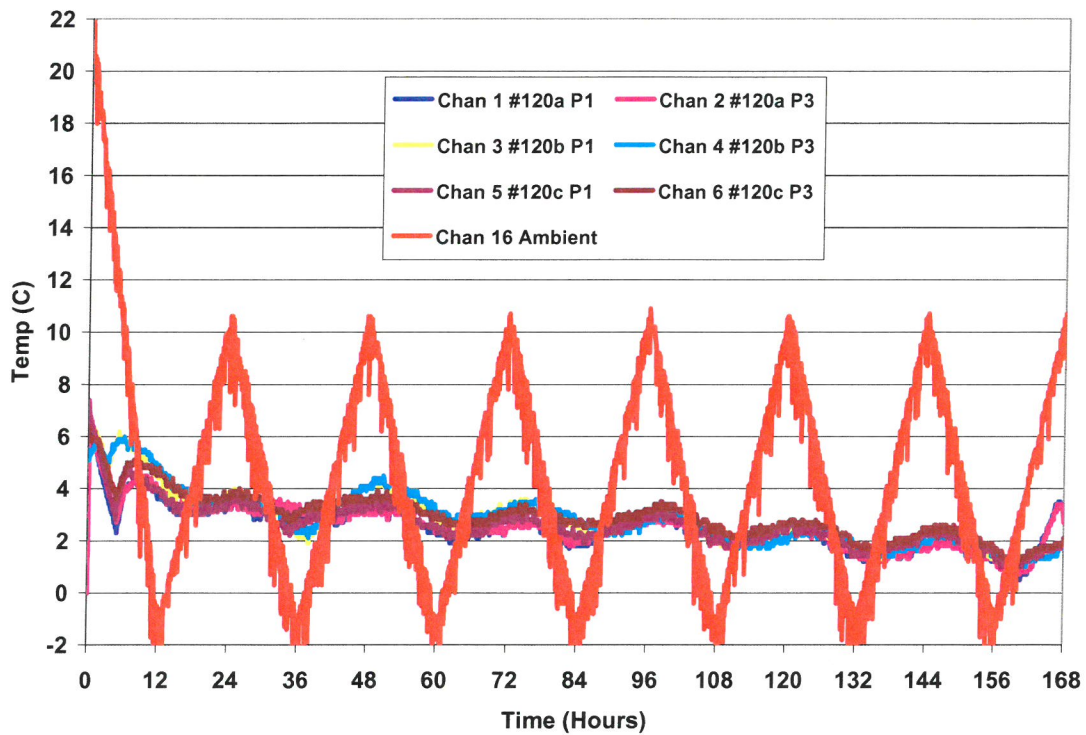


Table 12. Minimum and maximum temperature for the first 96 hours of test

	120a P1	120a P3	120b P1	120b P3	120c P1	1120c P3
Minimum Temperature	1.7	1.8	1.9	2.1	1.9	2.5
Maximum Temperature	6.3	5.8	6.6	6.0	7.1	6.0



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## **ISTA-3A Drop Test**

Three 2-153853A NanoCool shipping systems were tested against a modified ISTA-3A drop sequence (Table 2). All of the systems passed when checked against the acceptance criteria outlined on Page 6 of this report. The NanoCool cooler engines maintained vacuum and cooling properties. The insulation for all three systems maintained vacuum and there was no significant damage to the vacuum insulation panels.

## **Conclusion**

These tests have shown that the 2-153853A system maintains 2 to 8°C product temperature for a minimum of 96 hours for a wide range of ambient temperature profiles representing transit temperatures for a wide range of global temperature profiles. For several ambient profiles, the product temperatures remained within 2 and 8 °C for the full 168 hours of the test. Drop testing against the modified ISTA-3A drop sequence shows that the 2-153853A passed without any significant damage. These results are reported in good faith and the customer should use their judgment as to whether the system is appropriate for their application.

### **Liability Restriction:**


It should be noted that this report represents test results carried out by NanoCool LLC in good faith. As such we cannot be responsible for the handling and usage of the systems tested; we restrict our liability to the replacement of any components supplied which are not to agreed specification. Customers are advised to check the appropriateness of the testing parameters for their shipping conditions. As with any cool shipping system used in normal warehouse conditions some condensation will occur, we advise that the effect of this condensation on the product to be shipped is checked prior to usage.

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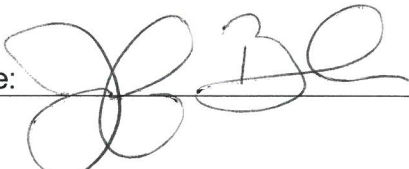
### Final QMOC/Protocol Approval

The signatures listed below indicate that these representatives have reviewed this document and approve of the QMOC/Protocol activities and data documented herein. When all approval signatures have been obtained, the QMOC/Protocol is considered complete.

#### Approved By

Signature:  Date: 4/27/16  
Product Development/Tech Services

Signature:  Date: 4/27/16  
Operations

Signature:  Date: 4/27/16  
Quality

Signature: See e-mail ww 4/27/16 Date: 4/27/16  
Sales

## Environmental Test Chamber Register

Description	Dimensions	Model #	Serial #	Calibrated	Manufacturer	Range
Test Chamber #2, Everette	38" x 38" x 38"	Z-Plus 32	ZPO453561	Annually	Cincinnati Sub- Zero	-20 °C to +50 °C
Test Chamber #3, Gordon	38" x 38" x 38"	Z-Plus 32	ZPO453562	Annually	Cincinnati Sub- Zero	-20 °C to +50 °C
Test Chamber #5, Sammi	30" x 30" x 30"	Z-Plus 16	ZP0553772	Annually	Cincinnati Sub- Zero	-20 °C to +50 °C
Register approved	Name ..... Wendy White Date ..... November 2011					

## Data Logger Register

Description	Note	Model #	Serial #	Calibrated	Manufacturer	Range
Data Logger Oscar	16 temp. channels, 1 pulse channel, 1 event channel	1025J	EL-7416	Annually	Eltek Instruments	-200 °C to +200 °C
Data Logger T-Boy	16 temp. channels, 1 pulse channel, 1 event channel	1025J	EL-8110	Annually	Eltek Instruments	-200 °C to +200 °C
Data Logger Rene	16 temp. channels, 1 pulse channel, 1 event channel	1025	EL-8173	Annually	Eltek Instruments	-200 °C to +200 °C
Data Logger Bubba	16 temp. channels, 1 pulse channel, 1 event channel	1025	EL-8174	Annually	Eltek Instruments	-200 °C to +200 °C
Register approved	Name ..... Wendy White Date ..... February 2012					