



Customer: FedEx Corporation
Document Type: Qualification Report
Product: 2-153853D-S
Document Date: 03 May 2016
Document Number: CQR-004-16 rev. 00

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Qualification Report For the 2-153853D-S NanoCool Shipping System

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Purpose

This report outlines testing for the qualification of the 2-153853D-S NanoCool shipping system. Three 2-153853D-S systems were tested against the ISTA-7D summer and winter forty-eight hour profiles (Chart 1) and three 2-153853D-S systems were drop tested against a modified ISTA-3A drop procedure.

Summary

Testing was conducted using the 2-153853D-S NanoCool shipping system. Three 2-153853D-S systems were tested against the ISTA-7D summer and winter forty-eight hour profiles (Chart 1) and three 2-153853D-S systems were drop tested against a modified ISTA-3A drop procedure (Chart 2). The product temperature ranged from 3.9 to 6.4°C during the ISTA summer test (FG85361-#70) and 1.8 to 6.6°C for the ISTA winter test (FG85361-#67). The product temperatures stayed within the 2-8°C specification for the entire forty-eight hours of the ISTA Summer test. During the winter test, two systems maintained 2-8°C for forty-eight hours and one maintained 2-8°C for 47.3 hours. The 2-153853D-S systems drop tested passed with no significant damage to the outer box, vacuum insulated panels (VIPs), or cooler engine.

Chart 1 - ISTA-7D 48 Hour Summer Profile

Summer		
Temperature °C	Hours	Elapsed Time
22	4	4
35	2	6
30	36	42
35	6	48
Winter		
Temperature °C	Hours	Elapsed Time
18	4	4
(-)10	2	6
10	36	42
(-)10	6	48

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Thermal Test Procedures

Testing was conducted using two cartons of 5mL vials, each carton holding ten vials, as a placebo product. All placebo products contained deionized water. A single vial out of the two cartons was probed with a thermocouple to monitor the product temperature during testing. The vial monitored was 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.

Hook-Up Procedure

- Open box and remove cooler
- Place cooler upside down, dome up, and activate
- Obtain two cartons of vials, one 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

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Down-loading 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 if the units passed or failed the 2-8°C product temperature specifications at forty-eight hours.
- Chamber used for test FG85361-#67 was ZP0553772; Logger: EL-8110
- Chamber used for test FG85361-#70 was ZP0453561; Logger: EL-7416

Drop Test Procedures

The purpose of this test is to evaluate the durability of the 2-153853D-S NanoCool shipping system. Three 2-153853D-S NanoCool shipping systems were drop tested against the ISTA-3A protocol (see Chart 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.

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Chart 2: Drop Sequence

ISTA 3A Drop Sequence		
Drop Number	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.

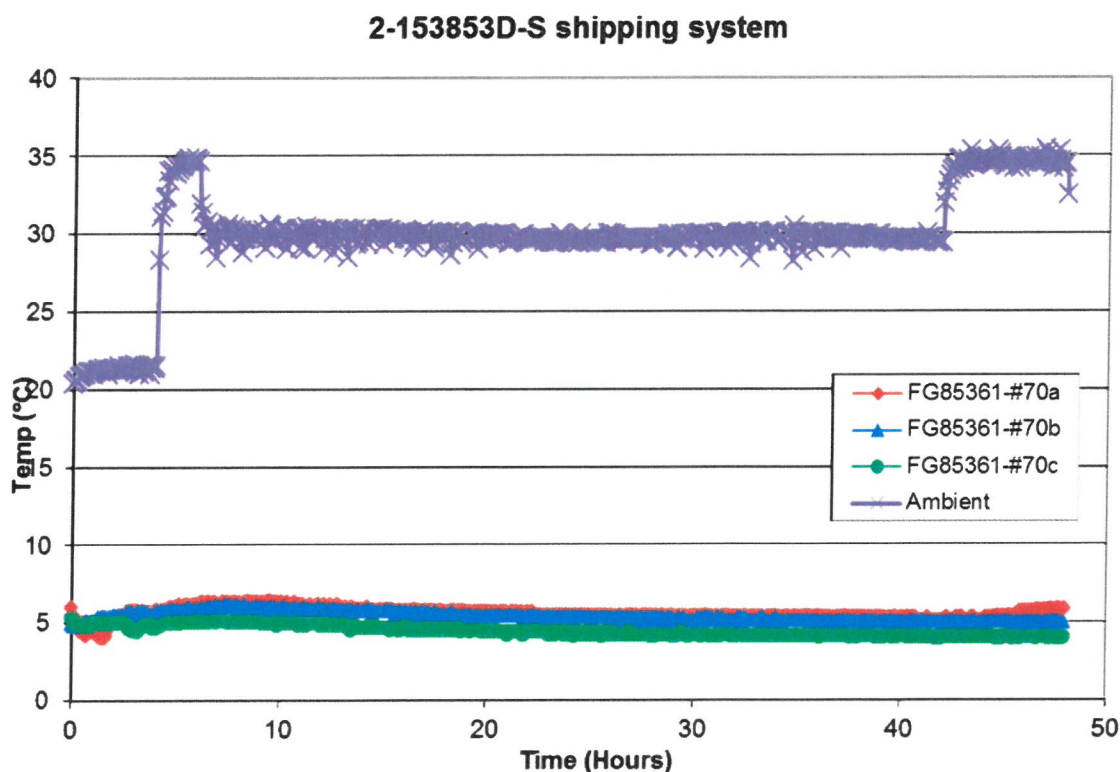
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Summary of Results

ISTA-7D 48 Hour Summer Profile

Test FG85361-#70 tested three 2-153853D-S NanoCool shipping systems. The test was performed against the ISTA-7D summer forty-eight hour profile (Graph 1). Two cartons of 5mL vials, each carton holding ten vials, were used as a placebo product. The product temperature stayed within the 2-8°C specification for the entire forty-eight hours of the test. The product temperature ranged from 3.9 to 6.4°C over the test. The average product temperature at forty-eight hours was 4.9°C.

Graph 1: ISTA-7D Summer

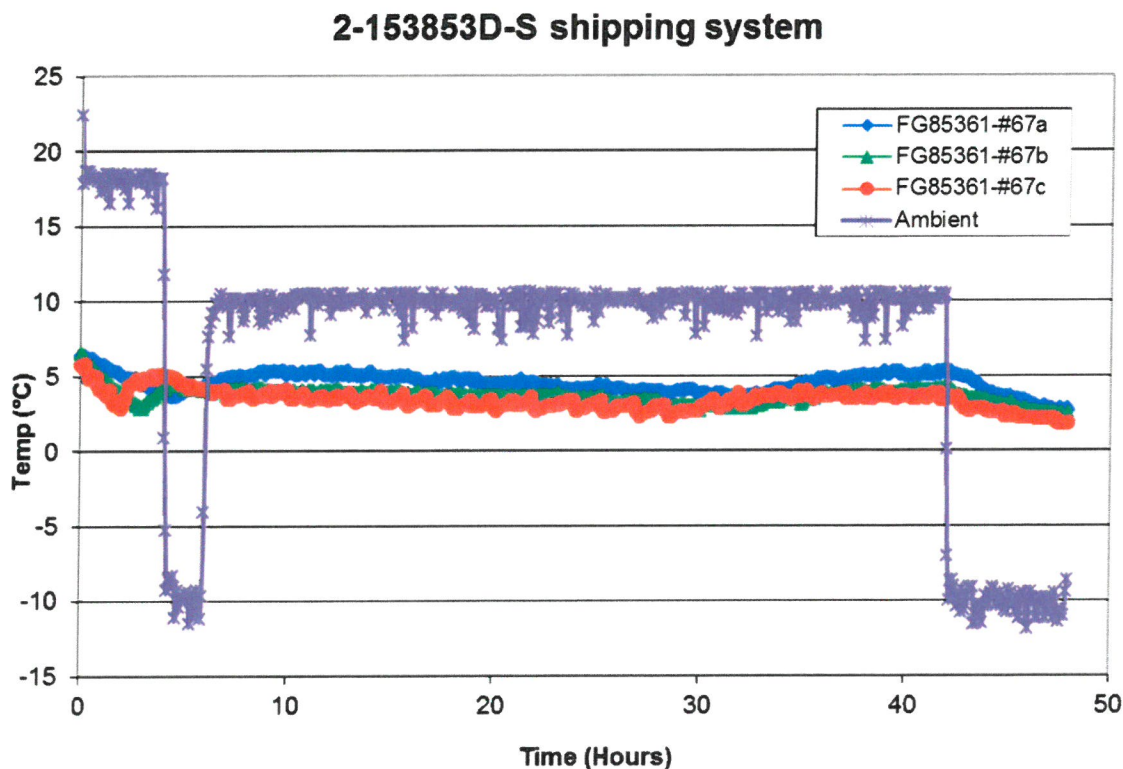


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ISTA-7D 48 Hour Winter Profile

Test FG85361-#67 tested three 2-153853D-S NanoCool shipping systems. The test was performed against the ISTA-7D winter forty-eight hour profile (Graph 2). Two cartons of 5mL vials, each carton holding ten vials, were used as a placebo product. All three systems maintained product temperatures between 2-8°C for 47.3 hours of the test. Two systems maintained 2-8°C for forty-eight hours and one system for 47.3 hours. The product temperature ranged from 1.8 to 6.6°C over the test. The average product temperature at forty-eight hours was 2.3°C.

Graph 2: ISTA-7D Winter



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Charts 3 and 4 list the maximum and minimum temperature recorded during testing. The forty-eight hour end product temperature is also noted. When a reading occurs more than once, the time of the first occurrence is shown.

Chart 3: ISTA-7D Summer

Test #	Profile	Minimum temperature recorded		Maximum temperature recorded		Temp. @ 48 Hours, °C
		Temp., °C	Time, Hours	Temp., °C	Time, Hours	
FG85361-#70a	Summer	4.0	1.4	6.4	8.5	5.9
FG85361-#70b	Summer	4.8	0.1	6.2	6.9	4.9
FG85361-#70c	Summer	3.9	41.8	5.3	0.0	4.0

Chart 4: ISTA-7D Winter

Test #	Profile	Minimum temperature recorded		Maximum temperature recorded		Temp. @ 48 Hours, °C
		Temp., °C	Time, Hours	Temp., °C	Time, Hours	
FG85361-#67a	Winter	2.6	47.7	6.4	0.0	2.7
FG85361-#67b	Winter	2.3	47.4	6.6	0.0	2.3
FG85361-#67c	Winter	1.8	47.5	5.9	0.2	1.8

ISTA-3A Drop Test

Three 2-153853D-S NanoCool shipping systems were tested against a modified ISTA-3A drop sequence (Chart 2). All of the systems passed when checked against the acceptance criteria outlined earlier in the 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 VIPs.

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Conclusion

These tests have shown that this system maintains 2 to 8°C for the entire length of the ISTA-7D forty-eight summer profile and for at least 47.3 hours when tested against the ISTA-7D forty-eight hour winter profile. Drop testing against the modified ISTA-3A drop sequence also shows that the system meets NanoCool's requirements for durability. 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.

Written By

Signature:  Date: 5/5/16
Product Development/Tech Services

Approved By

Signature:  Date: 5/4/16
Operations

Signature:  Date: 05/05/16
Quality

Signature:  Date: 5/4/16
Sales

Environmental Test Chamber Register

Description	Dimensions	Model #	Serial #	Calibrated	Manufacturer	Range
Test Chamber #2 Everette	38" x 38" x 38"	Z-Plus 32	ZP0453561	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	Wendy White		November 2012			
Name	Date					

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
Register approved	Wendy White		February 2013			
Name	Date					