

Pelican Products, Inc., the global leader in the design and manufacture of high-performance protective case solutions and advanced portable lighting systems, has rebranded its global temperature controlled packaging division. The Pelican BioThermal™ division combines two recently acquired companies, US based Minnesota Thermal Science, and UK based Cool Logistics.

The combination of the two companies allows Pelican BioThermal to offer a full range of packaging solutions to accommodate most temperature controlled shipping requirements. Pelican BioThermal's full suite of products and services offer longevity, reusability and sustainability to provide the safe transport of pharmaceuticals, tissue, diagnostics/clinical trials, vaccines and blood supplies.

The company name Minnesota Thermal Science, MTS Logo, and any brand identity are wholly owned by Pelican Products, Inc. This technical document was created prior to the creation of the Pelican BioThermal division. Any references of Minnesota Thermal Science, or MTS, are considered synonymous with Pelican BioThermal. The rebranding is effective as of October 1, 2014.








Series 4 – EMT ISTA Summer and Winter No Load Thermal Qualification Test Report

Prepared by
Minnesota Thermal Science, LLC

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MTS Test Report Number: TR-MTS-11-290-1 (Rev-A)
Final Report Release Date: 17 October 2011

| | | |
|--------------|--|--|
| Prepared By: | Reuben Helm Laboratory Technician |  17 OCT 11 |
| Approved By: | William T. Mayer Director of Engineering |  17 OCT 11 |
| Approved By: | Dick Peters Vice President, Operations |  Oct 17, 2011 |

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MTS Thermal Qualification Report

Title: Series 4 – EMT ISTA Summer and Winter No Load Thermal Qualification Test Report

Test Location: Minnesota Thermal Science, LLC
3020 Niagara Lane N.
Plymouth, MN 55447

Test Report Number: TR-MTS-11-290-1

Final Report Release Date: 17 October 2011

Test Start/End Date: 11OCT11 / 17OCT11

Report Revision Level: Rev-A

Referenced Documents: MTS Test I.D. #: 11-284-MTS001
11-287-MTS006

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1.0 Objective

The objective of the study was to investigate the amount of time the Series 4 – EMT shipping system could maintain internal payload area temperatures at or between 1°C and 10°C as well as at or between 2°C and 8°C while subjected to the ISTA Summer 24 hour cycled 7D shipping profile with hot shipping and hot receiving conditions and the ISTA Winter 24 hour cycled 7D shipping profile with cold shipping and cold receiving conditions. This study examined the shipper's performance without a payload.

2.0 Acronyms

MTS: Minnesota Thermal Science, LLC
ISTA: International Safe Transit Association
NIST: National Institute of Science and Technology
PCM: Phase Change Material
TIC: Thermal Isolation Chamber
VIP: Vacuum Insulation Panel

3.0 Definitions

Bench Time: The length of time immediately following TIC conditioning and before packout when the TIC system is removed from the freezer and allowed to sit at room temperature so that the PCM inside will rise to the operating temperature range.

Non-insulating Dunnage: Material designed to take up space without adding to the R-Value of the shipper. The non-insulating dunnage that was used in this test was 2" x 1" x 1" polyethylene foam strips.

Packout: The designed configuration for the temperature controlled package.

Payload: Product contained in the insulated shipper to mimic real load. This test was conducted to test the thermal properties of the shipper without a load therefore no payload was used.

Temperature Probe: A device which measures local temperature within a calibrated tolerance. The temperature probes used for this thermal operational qualification were Global Sensors calibrated LogTag data loggers.

Temperature profile: The temperature set points and exposure time experienced by the insulated shipper within the environmental chamber. The ISTA 7D Summer and ISTA 7D Winter 24 hour cycled temperature profiles were used for this qualification.

Thermal Operational Qualification: The action of qualifying a containers thermal capability under highly controlled conditions.

4.0 Executive Summary

A Series 4 – EMT shipping system was exposed to two different ambient temperature profiles, the ISTA 7D Summer 24 hour cycled temperature profile and the ISTA 7D Winter 24 hour cycled temperature profile. The study investigates the performance of the shipper without the additional thermal mass of a payload.

The test revealed that the Series 4 – EMT shipping system was able to maintain internal payload area temperatures at or between 1°C and 10°C for 53.92 hours under ISTA 7D Summer conditions, and for over 49.75 hours under ISTA 7D Winter conditions. The shipper was able to maintain temperatures in the range of 2°C and 8°C for 46.00 hours under ISTA 7D Summer conditions and for over 49.75 hours under ISTA 7D Winter conditions. Note that the ISTA Winter Test was stopped at 49.75 hours. There were no excursions outside the designated temperature ranges before the test was stopped in the ISTA Winter Profile. The performance results are summarized in Table 1 below referencing the first probe to have an excursion outside the required 2°C and 8°C range and 1°C and 10°C range.

| Series 4 – EMT ISTA Summer and Winter Thermal Performance | | | | | |
|---|----------------|---------|------------------|---------------------------|------------------|
| Shipper | Test Profile | Payload | TIC Conditioning | Temperature Range | In-Spec. Time |
| Series 4 - EMT | ISTA 7D Summer | None | -18°C | At or Between 1°C to 10°C | 53.92 Hours |
| | ISTA 7D Summer | None | -18°C | At or Between 2°C to 8°C | 46.00 Hours |
| | ISTA 7D Winter | None | -18°C | At or Between 1°C to 10°C | Over 49.75 Hours |
| | ISTA 7D Winter | None | -18°C | At or Between 2°C to 8°C | Over 49.75 Hours |

Table 1: Results summary for the Series 4 – EMT

5.0 Background

The Series 4 – EMT shipping system has a payload volume of approximately 2 liters with a tare weight of approximately 7.2 lbs. The internal payload area dimensions are 6" x 5" x 4.25". The container consists of a TIC with integrated PCM, a 0.65" VIP assembly and an outer bag container. The TIC system consists of a base with lid. The VIP assembly is made up of six panels that are encapsulated and assembled into a base with a lid. The outer container is constructed

out of a durable fabric and is secured with a metal zipper. It comes equip with a carrying handle and a document pouch. The outer dimensions of the container are 9.25" x 8.25" x 8.0" (see appendix [a] for configuration illustrations).

6.0 Materials and Equipment Used

6.1 Equipment List:

- Calibrated ESPEC ESX-4CA Programmable Environmental Chamber
- Chest Freezer Model No. GLFC2528FW1
- Series 4 – EMT Shipping System
- Non-insulating Dunnage
- NIST Traceable Global Sensors calibrated LogTag Data Loggers
- Canon Power Shot A3100 Digital Camera with Image Stabilizer

6.2 Equipment Calibration:

The LogTag temperature data loggers meet or exceeds the standards stated in ASTM D3103 and ISTA procedure 7D. The temperature data loggers have a temperature resolution of 0.1°C and a temperature accuracy of $\pm 1^\circ\text{C}$ over the test range. The environmental chamber temperature controller is also calibrated to a temperature accuracy of $\pm 1^\circ\text{C}$ over the chambers entire temperature range. Copies of the calibration certificates can be found in appendix f.

7.0 Test Plan outline

Table 2 below outlines the test plan for the thermal testing of the Series 4 – EMT Shipping System.

| Series 4 – EMT Shipping System Test Plan Outline | | | | | | | |
|---|----------------|--------------|---------------------|----------------|------------------|----------------------|---------|
| Test Run # | Shipper | Test Chamber | Temperature Profile | Insulator Type | TIC Conditioning | Payload Conditioning | Payload |
| 1 | Series 4 - EMT | ESX-4CA | ISTA 7D Winter | VIP | -18.0°C | N/A | None |
| 2 | Series 4 - EMT | ESX-4CA | ISTA 7D Summer | VIP | -18.0°C | N/A | None |

Table 2: Testing and Preparation Conditions for Series 4 – EMT

8.0 Procedures

The procedures described in this section outline the necessary steps to setup and test the thermal performance of the Series 4 – EMT Shipping systems.

8.1 TIC Conditioning

The Series 4 – EMT TIC system was removed from the insulator assembly and placed into a chest freezer set to -18°C for a minimum of 24 hours before each test run. The PCM was solid after conditioning.

8.2 Probe placement

Two Global Sensors calibrated LogTag Data Loggers were used to record temperatures for each test. One probe was used for monitoring the interior of the container and one was used for monitoring the test ambient conditions. Temperature probe #1 was secured to non-insulating dunnage and placed in the center and on the bottom of the payload area. Temperature probe #2 was placed inside the environmental chamber record the test ambient conditions. See figure 1 below for an illustration of the probe placement.

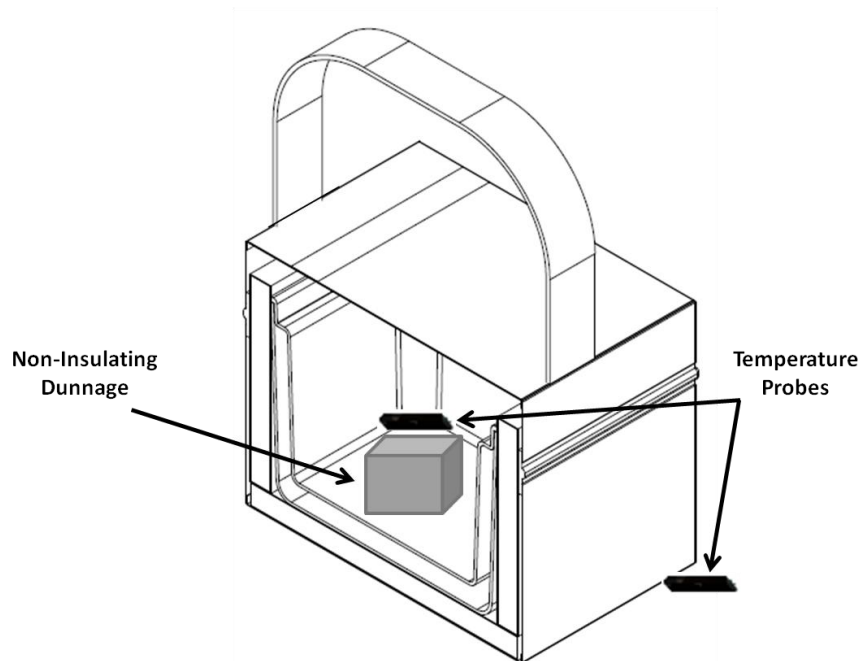


Figure 1: Probe Placement Diagram

8.3 Payload

The main payload intended to be used in the shippers is blood for the 1° C to 10° C range and chilled medical supplies or pharmaceuticals for the 2° C to 8° C range. This test was conducted without a payload therefore no payload conditioning was required.

8.4 Shipper Packout

The TIC system was removed from the -18°C freezer after a minimum of 24 hours of conditioning time. It was then given a bench time at room temperature (22°C ±3°C) for approximately 20 to 30 minutes. After the bench time the TIC base was loaded into the insulator assembly. Non insulating dunnage was placed in the center and on the bottom of the payload area space. Both temperature probes were then activated. Probe #1 was placed on top of the dunnage. The TIC lid was placed on top of the base and the VIP lid was set onto the rest of the insulator assembly. The Velcro strap, which is attached to the outer bag, was fastened around the VIP assembly. The outer container was closed and secured using the provided zipper. The shipper was loaded into the environmental chamber. Probe #2 was placed into the chamber to record external test ambient conditions. The data loggers were set up so that the temperature readings were recorded in 5 minute intervals. The environmental chamber was set to run the desired temperature profile and started.

8.5 Temperature Profiles

The temperature profiles listed below were used for the thermal performance testing of the shippers. Note: it will take up to 10 minutes (0.17 hours) to change temperatures due to environmental chambers temperature change rate limitations. The change rate for the environmental chambers is a maximum of 5°C per minute.

8.5.1 ISTA 7D Summer Temperature Profile

| Step Number | Temp (° C) | Temp (°F) | Duration (Hours) | Total Time (Hours) |
|-------------|------------|-----------|------------------|--------------------|
| 1 | 22.0 | 71.6 | 4 | 4 |
| 2 | 35.0 | 95.0 | 2 | 6 |
| 3 | 30.0 | 86.0 | 12 | 18 |
| 4 | 35.0 | 95.0 | 6 | 24 |

Table 3: ISTA 7D Summer 24 Hour cycled temperature profile

The 24 hour summer profile was cycled continuously until the shipper encountered a temperature excursion.

8.5.2 ISTA 7D Winter Temperature Profile

| Step Number | Temp (° C) | Temp (°F) | Duration (Hours) | Total Time (Hours) |
|-------------|------------|-----------|------------------|--------------------|
| 1 | 18.0 | 64.4 | 4 | 4 |
| 2 | -10.0 | 14.0 | 2 | 6 |
| 3 | 10.0 | 50.0 | 12 | 18 |
| 4 | -10.0 | 14.0 | 6 | 24 |

Table 4: ISTA 7D Winter 24 Hour cycled temperature profile

The 24 hour winter profile was cycled over two times without failure.

9.0 Results

The test revealed that, without a payload, the Series 4 – EMT Shipping system was able to maintain internal payload area temperatures at or between 1°C and 10°C for 53.92 hours under ISTA 7D Summer conditions, and for over 49.75 hours under ISTA 7D Winter conditions. The shipper was able to maintain temperatures in the range of 2°C and 8°C for 46.00 hours under ISTA 7D Summer conditions and for over 49.75 hours under ISTA 7D Winter conditions. Note that the ISTA Winter Test was stopped at 49.75 hours. There were no excursions outside the designated temperature ranges before the test was stopped in the ISTA Winter Profile. The performance results are summarized in Table 5 below referencing the first probe to have an excursion outside the required 2°C and 8°C range and 1°C and 10°C range. Thermal performance graphs can be found in appendix e.

| Series 4 – EMT ISTA Summer and Winter Thermal Performance | | | | | | |
|---|----------------|---------|--------------|-------------------|--------------------------|---------------------------|
| Shipper | Test Profile | Payload | Lowest Temp. | Temp. at 48 Hours | 2°C to 8°C In-Spec. Time | 1°C to 10°C In-Spec. Time |
| Series 4 – EMT | ISTA 7D Summer | None | 1.5°C* | 8.1°C | 46.00 Hours | 53.92 Hours |
| | ISTA 7D Winter | None | 4.1°C | 4.4°C | Over 49.75 Hours | Over 49.75 Hours |

Table 5: Thermal Performance for Series 4 – EMT

*Note: The low temperature is influenced by the amount of bench time the TIC received after conditioning.

10.0 Equipment/Setup Pictures



Figure 2: ESPEC ESX-4CA



Figure 3: LogTag Temperature Data Logger



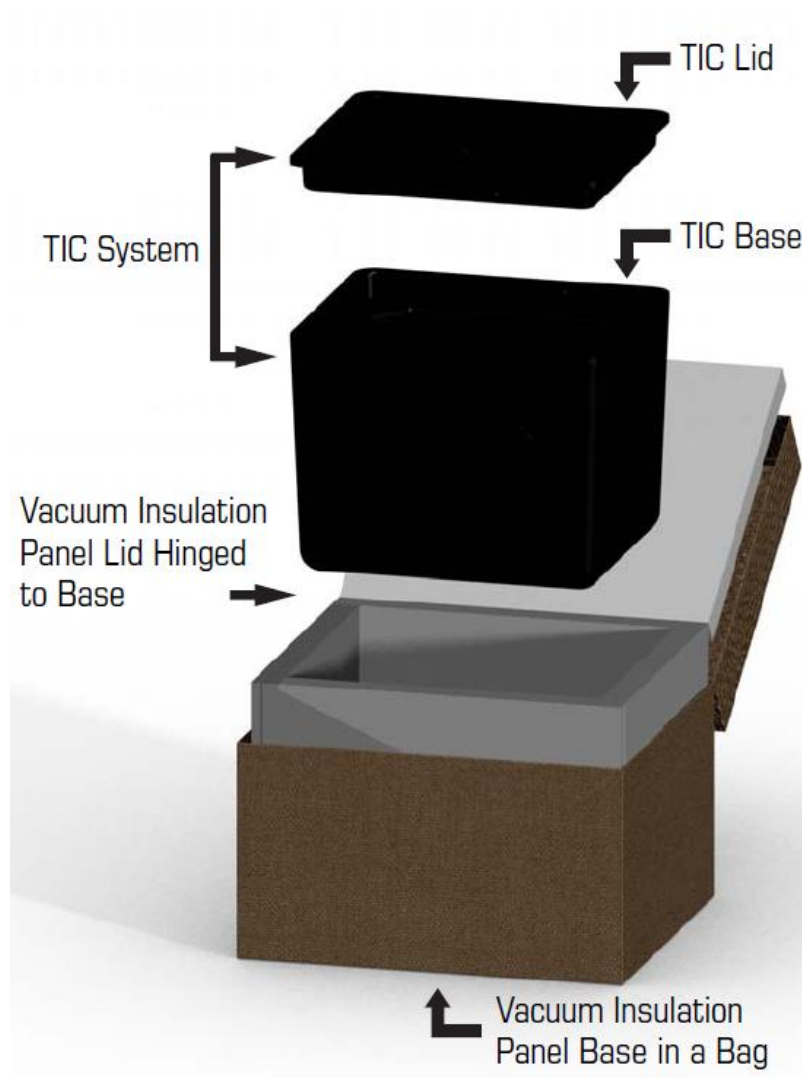
Figure 4: -18°C Chest Freezer



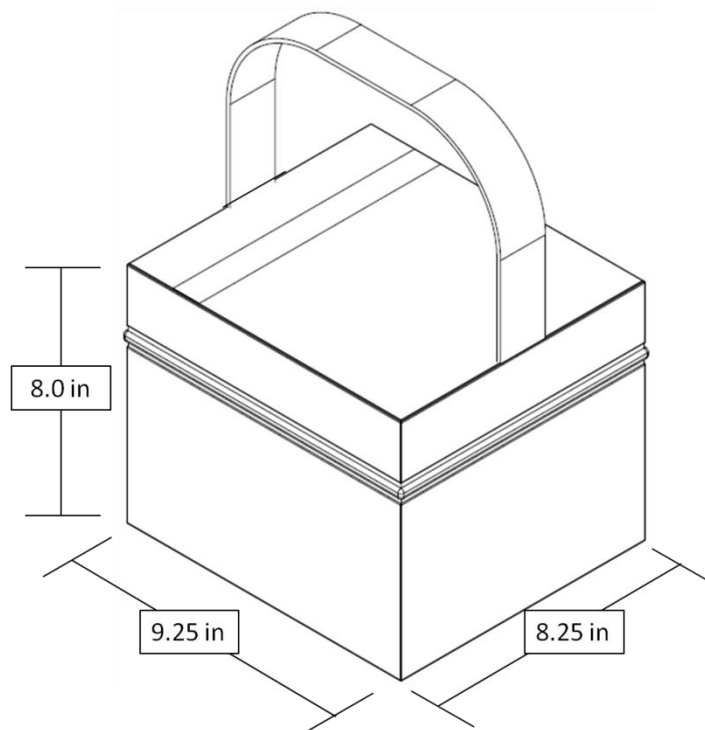
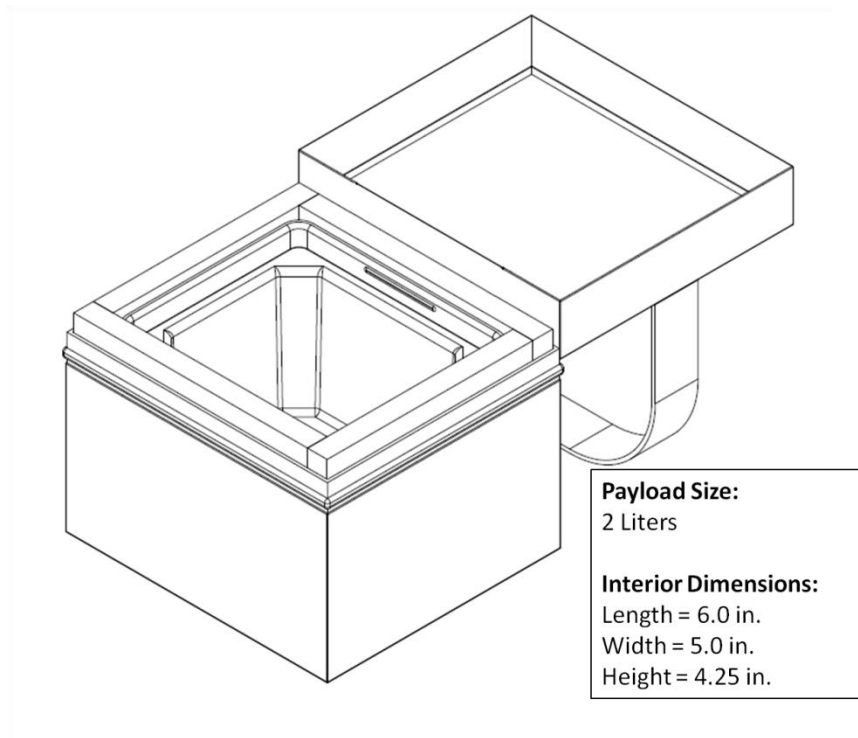
Figure 5: Series 4 – EMT Shipping System

11.0 Appendix

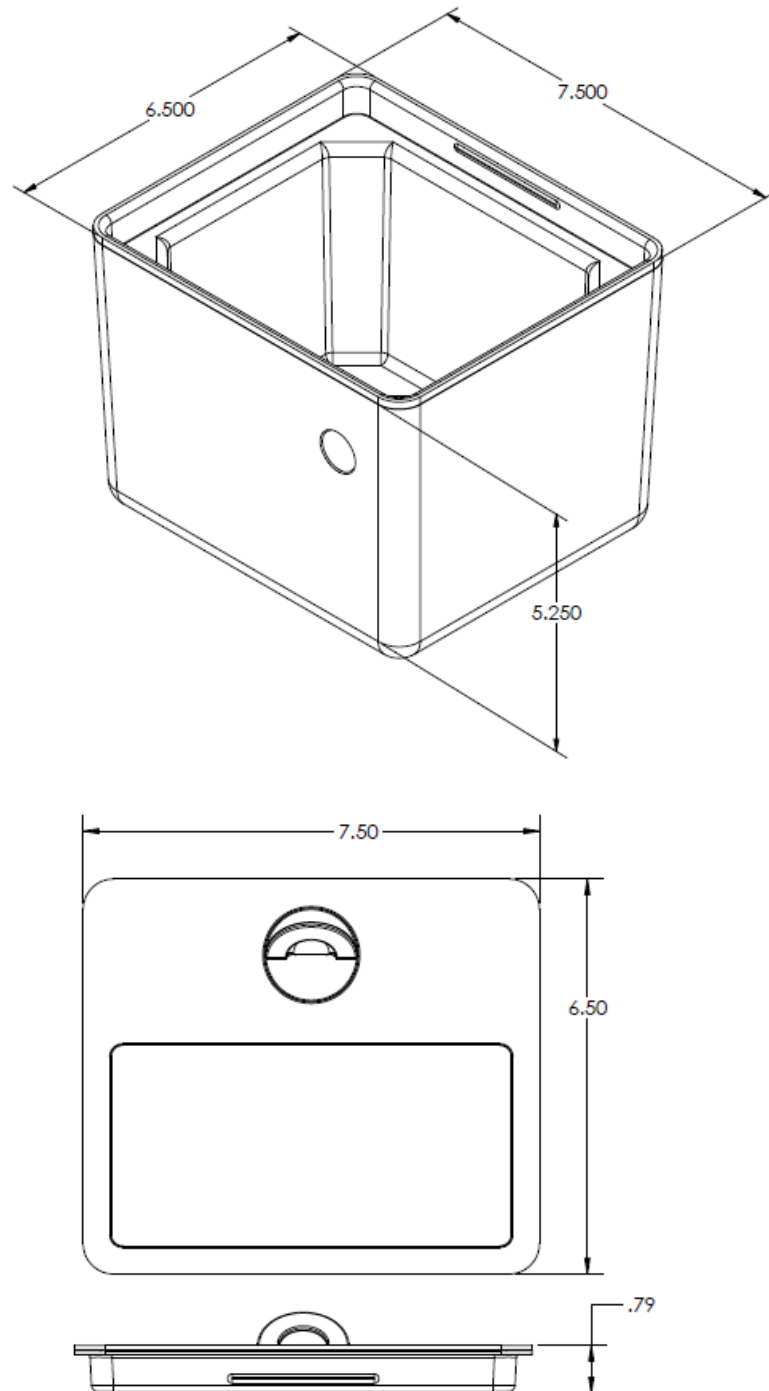
a. Series 4 - EMT shipper packout configuration



b. Series 4 - EMT shipper dimensions



c. Series 4 - EMT TIC dimensions



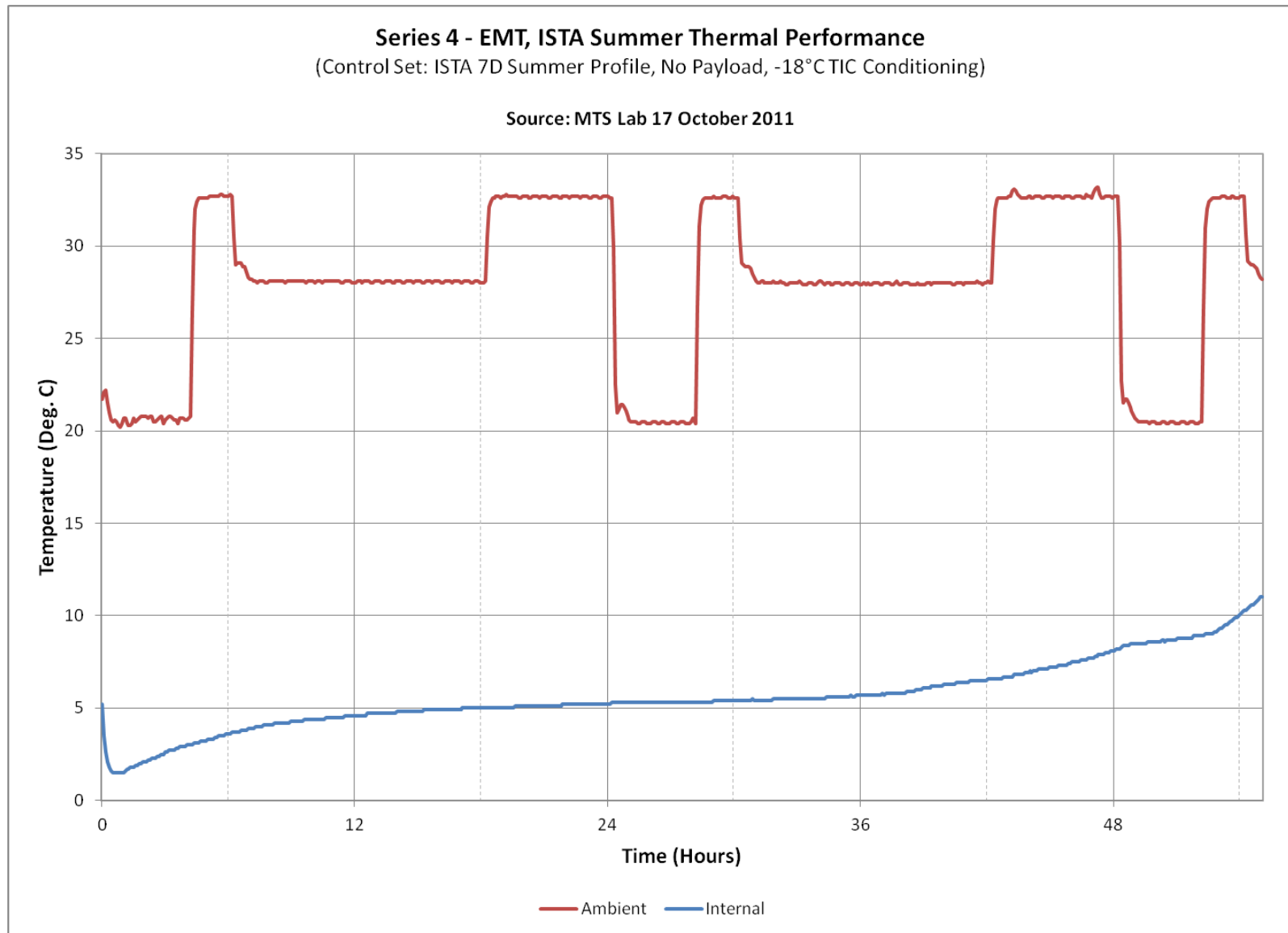
d. Test/Reference Instrument List

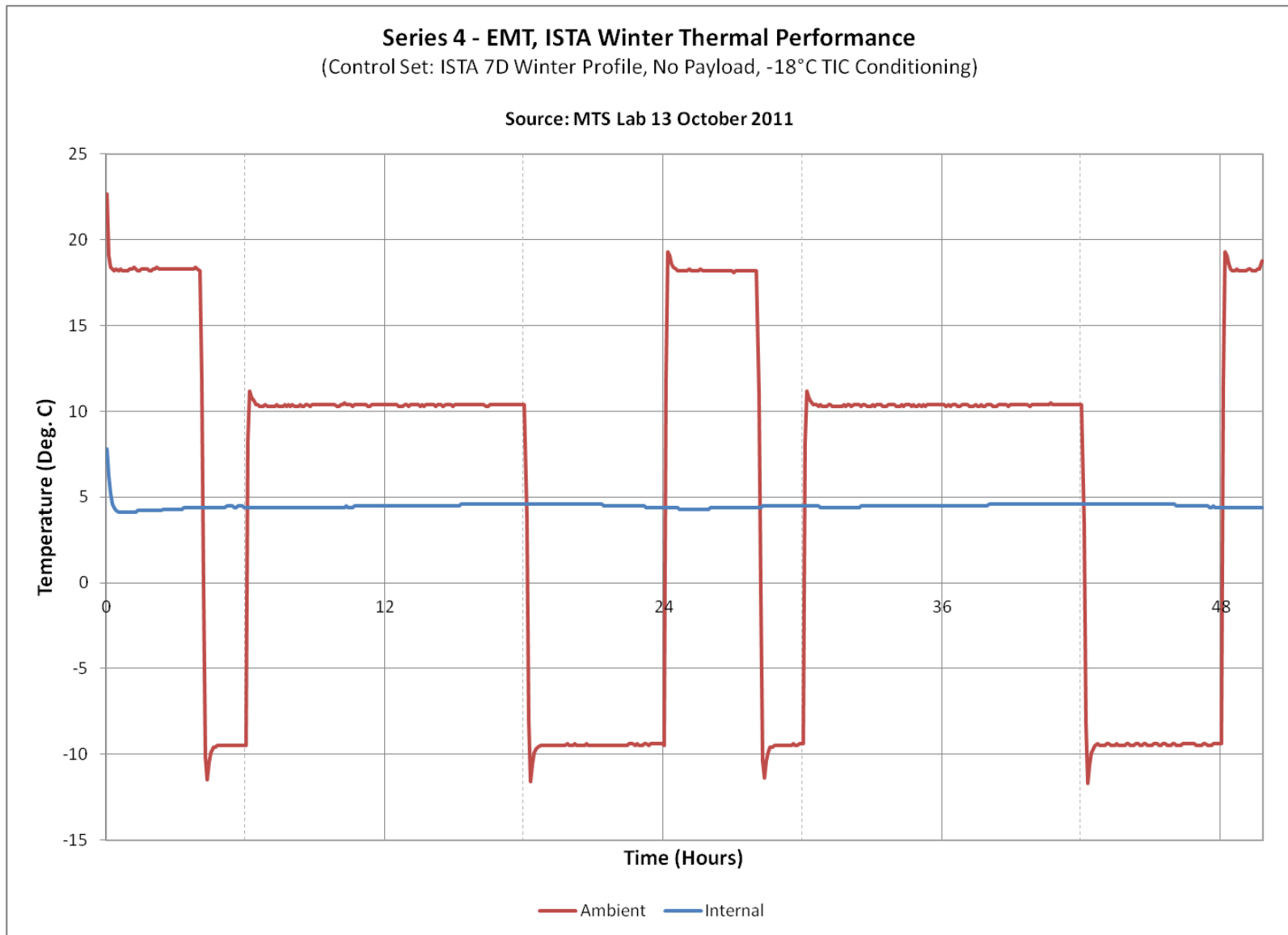
NOTE: Make additional copies as needed

Page 1 of 1

| Instrument Name | Mfg., Model No. Serial No. | Use | Cal. Date | Cal. Due Date | Cal. Cert. Attached? (Y/N) |
|-------------------------------------|--|------------------------------------|-----------|---------------|----------------------------|
| ESPEC ESX-4CA Environmental Chamber | Mfg: <u>ESPEC North America Inc.</u> Model #: <u>ESX-4CA</u> Serial #: <u>018259</u> | Thermal Testing of Shipper | 08APR11 | 08APR12 | Y |
| LogTag Temperature Data Logger | Mfg: <u>Global Sensors</u> Model #: <u>TRIX-8</u> Serial #: <u>8800016843</u> | Recording Ambient Test Conditions | 10DEC10 | 10DEC11 | Y |
| LogTag Temperature Data Logger | Mfg: <u>Global Sensors</u> Model #: <u>TRIX-8</u> Serial #: <u>8800016844</u> | Recording Internal Test Conditions | 10DEC10 | 10DEC11 | Y |
| LogTag Temperature Data Logger | Mfg: <u>Global Sensors</u> Model #: <u>TRIX-8</u> Serial #: <u>8800018733</u> | Recording Ambient Test Conditions | 29MAR11 | 29MAR12 | Y |
| LogTag Temperature Data Logger | Mfg: <u>Global Sensors</u> Model #: <u>TRIX-8</u> Serial #: <u>8800018734</u> | Recording Internal Test Conditions | 29MAR11 | 29MAR12 | Y |
| | Mfg: _____ Model #: _____ Serial #: _____ | | | | |
| | Mfg: _____ Model #: _____ Serial #: _____ | | | | |
| | Mfg: _____ Model #: _____ Serial #: _____ | | | | |

e. Thermal Performance Graphs





f. Equipment Certifications

Equipment Certifications



SUPERIOR
MECHANICAL SYSTEMS INC.

CALIBRATION DATA / TEST SHEET

Certificate #: 4811014259

Customer: Minnesota Thermal Science

Customer ID #: 001047

MANUFACTURE: Espec

INSTRUMENT: Controller

EQUIPMENT MODEL NO.: ESX-4CA

MANUFACTURER: Espec

EQUIPMENT SERIAL NO.: 018259

MODEL: SCP-220

CALIBRATED BY: Byron Phelps

SERIAL NO.: OALG5H-0776-A-06

CALIBRATED DATE: 4-8-2011

CALIBRATION PROCEDURE: Input TC and Verify

RECALIBRATED DATE: 4-8-2012

DATE OF LAST SERVICE: 4-15-10

APPROVED BY: Bill W

INITIAL FINDINGS: 1. Within Acceptance Tolerance ☒
2. Outside Acceptance Tolerance ☐

CALIBRATING INSTRUMENT: Process Calibrator

MANUFACTURER: Fluke

FINAL FINDINGS: 1. Within Acceptance Tolerance ☒
2. Outside Acceptance Tolerance ☐

MODEL: 725

SERIAL NO.: 7832093

CERTIFICATION DATE: 11-9-2010

RECALL DATE: 11-9-2011

CERTIFICATION #: 7832093

| FUNCTION TESTED | NOMINAL VALUE | OBSERVATION | | CALIBRATION LIMITS |
|-----------------|---------------|-------------|-------|--------------------|
| | | INITIAL | FINAL | |
| Channel 1 | -70.0 | -69.7 | -69.7 | $\pm .5$ |
| Type T | 0.0 | 0.1 | 0.1 | $\pm .5$ |
| | 170.0 | 170.0 | 170.0 | $\pm .5$ |
| Channel 2 | -70.0 | -69.9 | -69.9 | $\pm .5$ |
| Type T | 0.0 | 0.0 | 0.0 | $\pm .5$ |
| | 170.0 | 170.0 | 170 | $\pm .5$ |
| Product temp | -70.0 | -69.9 | -69.9 | $\pm .5$ |
| Type T | 0.0 | -0.1 | -0.1 | $\pm .5$ |
| | 170.0 | 169.9 | 169.9 | $\pm .5$ |

| Verify | Controller | Temperature | RM temp | Verifying Meter | Temperature | RM temp |
|---------|------------|-------------|---------|-----------------|-------------|---------|
| | -10 | -12.2 | | M/N 725 | -11.6 | |
| | 35 | 32.6 | | S/N 7832093 | 33.2 | |
| | -10/35 | -11.2/34.9 | | Cert # 7832093 | | |
| Product | | | | Duc 11-9-2011 | | |

REMARKS (LIST ANY ABNORMALITIES FOR OUTSIDE OF ACCEPTANCE TOLERANCE): See Back of Pg

1244 60th Avenue NW · Suite C · Rochester, Minnesota 55901 tel: 507.289.5126 fax: 507.281.9807

Heating, Ventilation, Air Conditioning & Refrigeration



Global Sensors, LLC

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info@global-sensors.com

www.global-sensors.com

CERTIFICATION OF ACCURACY

This is to certify that the instrument noted below has been tested in our laboratory using controlled temperature and humidity equipment with NIST certified test thermometers as the primary reference. Global Sensors verifies temperature and humidity of the instruments by placing the units in a temperature and humidity test chamber that has been certified for accuracy by an outside testing authority. The loggers are programmed and the recorded readings are compared with the recorded readings of a precision reference thermometer, which is traceable to the NIST.

Customer Information

Minnesota Thermal Science, LLC

3020 Niagara Lane

Plymouth, MN 55447

Certification Details

Certification Number: 20101210-8800016843 Certification Date: December 10, 2010

Re-Certification Date: December 10, 2011

Instrument Details:

Model Type: LogTag Multi-use Permanent Memory Temperature Recorder With One Temperature Sensor

Product Code: LogTag-M

Serial Number: 8800016843

Condition: Used/Good

Environmental Details:

Temperature: 22.5°C

Humidity: 51%RH

Physical Inspection of the Instrument

This unit has been inspected for evidence of damage and functionality and has been found to be suitable for calibration.

Reference Instrument Details

| Calibration Equipment | | | | |
|-----------------------|-----------------|------------|----------------|----------------------|
| Manufacturer | Model No. | Serial No. | Date Certified | Recertification date |
| Digitron | 2008T7 | 43129851 | 06/11/10 | 06/11/11 |
| Certificate Number | NIST Reference. | | | |
| 244185 | 1263471082 | | | |

Calibration Results

| Calibration Accuracy | | | | |
|----------------------|------------------|--------------------|------------|----------|
| Serial Number: | Reference Point: | Indicated Reading: | Deviation: | Results: |
| 8800016843 | 0.0°C | 0.2°C | +0.2°C | Passed |
| | 40.0°C | 39.9°C | -0.1°C | Passed |

Certified Authority:

David Caskey
President

12/10/2010
Date

Verified By:

Chuck Gardner
Sales Manager

12/10/2010
Date





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3020 Niagara Lane
Plymouth, MN 55447

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Re-Certification Date: December 10, 2011

Instrument Details:

Model Type: LogTag Multi-use Permanent Memory Temperature Recorder With One Temperature Sensor
Product Code: LogTag-M Serial Number: 8800016844 Condition: Used/Good

Environmental Details:

Temperature: 22.5°C Humidity: 51%RH

Physical Inspection of the Instrument

This unit has been inspected for evidence of damage and functionality and has been found to be suitable for calibration.

Reference Instrument Details

| Calibration Equipment | | | | |
|-----------------------|-----------------|------------|----------------|----------------------|
| Manufacturer | Model No. | Serial No. | Date Certified | Recertification date |
| Digitron | 2008T7 | 43129851 | 06/11/10 | 06/11/11 |
| Certificate Number | NIST Reference. | | | |
| 244185 | 1263471082 | | | |

Calibration Results

| Calibration Accuracy | | | | |
|----------------------|------------------|--------------------|------------|----------|
| Serial Number: | Reference Point: | Indicated Reading: | Deviation: | Results: |
| 8800016844 | 0.0°C | 0.2°C | +0.2°C | Passed |
| | 40.0°C | 40.2°C | +0.2°C | Passed |

Certified Authority:


David Caskey
President
12/10/2010
Date

Verified By:


Chuck Gardner
Sales Manager
12/10/2010
Date





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Customer Information

Minnesota Thermal Science

Certification Details

Certification Number: 20110329-8800018733

Certification Date: March 29, 2011

Re-Certification Date: March 29, 2012

Instrument Details:

Model Type: LogTag Permanent Memory Temperature Recorder With One Temperature Sensor

Product Code: LogTag-M

Serial Number: 8800018733

Condition: Used

Environmental Details:

Temperature: 72.1°F

Humidity: 52%RH

Physical Inspection of the Instrument

This unit has been inspected and was found to be suitable for calibration.

Reference Instrument Details

| Calibration Equipment | | | | |
|-----------------------|-----------------|------------|----------------|----------------------|
| Manufacturer | Model No. | Serial No. | Date Certified | Recertification date |
| Digitron | 2008T7 | 431259851 | 06/11/10 | 06/11/11 |
| Certificate Number | NIST Reference. | | | |
| 244185 | CS-05-128 | 1263471082 | | |

Calibration Results

| Calibration Accuracy | | | | |
|----------------------|------------------|--------------------|------------|----------|
| Serial Number: | Reference Point: | Indicated Reading: | Deviation: | Results: |
| 8800018733 | 36.0°F | 36.2°F | +0.2°F | Passed |
| | 98.5°F | 98.7°F | +0.2°F | Passed |

Certified Authority:

David Caskey
President

3/29/11
Date

Chuck Gardner
Technical/Sales Manager

3/29/11
Date





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CERTIFICATION OF ACCURACY

This is to certify that the instrument noted below has been tested in our laboratory using controlled temperature and humidity equipment with NIST certified test thermometers as the primary reference. Global Sensors verifies temperature of the instrument by placing the units in a temperature and humidity test chamber that has been certified for accuracy by an outside testing authority. The loggers are programmed and the recorded readings are compared with the recorded readings of a precision reference thermometer, which is traceable to the NIST. The loggers are programmed and the recorded readings are compared with the recorded readings of the precision reference thermometer. External sensors are stabilized for at least 10 minutes, internal sensors for at least 45 minutes prior to taking readings for comparison.

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Certification Details

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Certification Date: March 29, 2011

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Model Type: LogTag Permanent Memory Temperature Recorder With One Temperature Sensor

Product Code: LogTag-M

Serial Number: 8800018734

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Humidity: 52%RH

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This unit has been inspected and was found to be suitable for calibration.

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|-----------------------|-----------------|------------|----------------|----------------------|
| Manufacturer | Model No. | Serial No. | Date Certified | Recertification date |
| Digitron | 2008T7 | 431259851 | 06/11/10 | 06/11/11 |
| Certificate Number | NIST Reference. | | | |
| 244185 | CS-05-128 | 1263471082 | | |

Calibration Results

| Calibration Accuracy | | | | |
|----------------------|------------------|--------------------|------------|----------|
| Serial Number: | Reference Point: | Indicated Reading: | Deviation: | Results: |
| 8800018734 | 36.0°F | 35.9°F | -0.1°F | Passed |
| | 98.5°F | 98.6°F | +0.1°F | Passed |

Certified Authority:

David Caskey
President

3/29/11
Date

Chuck Gardner
Technical/Sales Manager

3/29/11
Date

