Meeting the Challenges of Thermal Packaging

Despite an increased quantity of available solutions and overall improved effectiveness of temperature sensitive packaging, validating effectiveness of these solutions and comparing performance between several solutions is challenging for many teams. Several techniques including the ISTA 5B summer and winter profiles will be presented to compare and optimize off the shelf as well as custom packaging solutions for performance, size, weight and cost will be covered along with identification of common validation pitfalls.

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Despite an increased quantity of available solutions and overall improved effectiveness of Cold Chain packaging, validating effectiveness of these solutions and comparing performance between several solutions is challenging for many teams. Several techniques including the ISTA 5B summer profile will be presented to compare and optimize off the shelf as well as custom packaging solutions for performance, size, weight and cost along with the identification of common validation pitfalls. Ultimately, a model will be introduced as a way to determine the thermal resistance of the package system and then correlate the performance to the expected temperature extremes in the environment.

Several types of thermal packages

Cold Chain packaging is the ability to maintain the integrity of temperature sensitive products from the point of manufacture to the point of distribution or end-use. Once they have left the point of manufacture, the product temperature must be maintained and is typically shipped using express or overnight shipment. The required duration that a thermal package will need to maintain the temperature of the product may vary widely from 48 to 96 hours or even longer. Product temperature can be maintained by using either an active system or a passive system. Active thermal packaging requires some type of heat pump or mechanical system and may be beneficial in a closed loop distribution system. These packages have the ability to be reused, but are costly when compared to a passive system. Passive systems typically use a coolant such as gel packs or dry ice and are classified as frozen or refrigerated. For the purposes of this paper we will focus on refrigerated packaging that maintains a range of temperature from +2 to +8°C.

Products that require temperature control between +2 to +8°C can be vaccines or protein therapies where the effectiveness of these treatments degrade rapidly when exposed to temperature excursions outside this range. The challenge has been for passive systems to maintain the internal temperature of the product long enough through a distribution environment with unknown temperature extremes and duration of exposure. In addition, these systems need to achieve this goal at reasonable cost and weight along with a simple pack-out procedure to eliminate errors. Developing and validating a thermal package system is a long process and for many teams composed mostly of trial and error. This paper will address pitfalls associated with thermal packaging that may improve a current package design, consider thermal profiles, and provide a model to more rapidly determine the thermal resistance of a package system and predict the ability of a system to protect the product.

Background

The trade off for thermal packaging is cost, not only for the package but for the associated shipping costs and disposal costs; therefore, optimization of the thermal package is necessary. Variables to consider are time in transit, temperature extremes, package size, and thermal resistance. Review of basic heat transfer concepts and minimizing the effects will help build a better thermal design.

Heat transfer occurs through three mechanisms, conduction, convection, and radiation. Minimizing heat loss through conduction is achieved by the thickness of the insulation used. Convection occurs in two locations; within the package system and outside the package system. Internal convection will take place as the coolant continues to remove heat from the product. Heat loss due to air exchange from outside of the package is critical and linked to the quality of the container construction. Heat transfer due to radiation can be reduced with the use of reflective surfaces, but cannot be eliminated completely. Cost efficiency of reflective surfaces within the package may also be a limiting factor.

Coolant, in the form of gel packs, must have the ability to absorb large quantities of energy while maintaining a constant temperature. Material phase change (solid to liquid) of the coolant is the means by which absorption of energy is accomplished. Unfortunately, most gel packs are made from water or saline. These have a phase change at 0C which of course is below our +2 to +8°C range. Direct contact with the product is not recommended and may cause a portion of the product to freeze. Ideally, we would like to have a coolant with a phase change within the temperature range of our product. However, coolant with phase change characteristics within the +2 to +8°C range are made of toxic materials. Rupture of the coolant would be too high of a risk for a medical product. The shape of the coolant can also have a dramatic effect during pack-out if the package design requires flat gel packs.

Insulation is the primary means of slowing heat transfer due to conduction. Common materials are rigid polyurethane foam, or expanded polystyrene. Other elaborate materials are also available, but are usually more expensive. An insulated container should be made of lightweight yet dense material and should have the ability to be sealed. Issues with cracking due to impacts will compromise the effectiveness at reducing thermal transfer.

ISTA 5B and the distribution environment

The distribution environment is the largest unknown variable in the equation of the thermal package system. Seasonal changes have a dramatic effect on temperature exposure and require developing a thermal pack for a wide temperature range. ISTA 5B recommends a study of the distribution environment monitoring all trip segments, but statistical significance comes into play when trying to measure the environment. Several trips would have to be recorded between all major distribution hubs, assuming a nationwide customer base. If the product is distributed globally the number of required measurements increases exponentially. This does not take into account the trips required to monitor the varying seasonal changes. Other data collected by LTL carriers would be helpful, but is often difficult to obtain. Doing a search on the web for temperature extremes yields many sites with data collected worldwide.

Once the data is obtained incorporating the temperature extremes into a thermal profile will be a good approximation for use in validating the package system. However, determining duration of exposure at a temperature extreme is difficult if not impossible. Therefore, we look to standards organizations, like ISTA to make recommendations. But even these recommendations can be extreme. Two thermal packs used for this study were subjected to the ISTA 5B thermal profile.

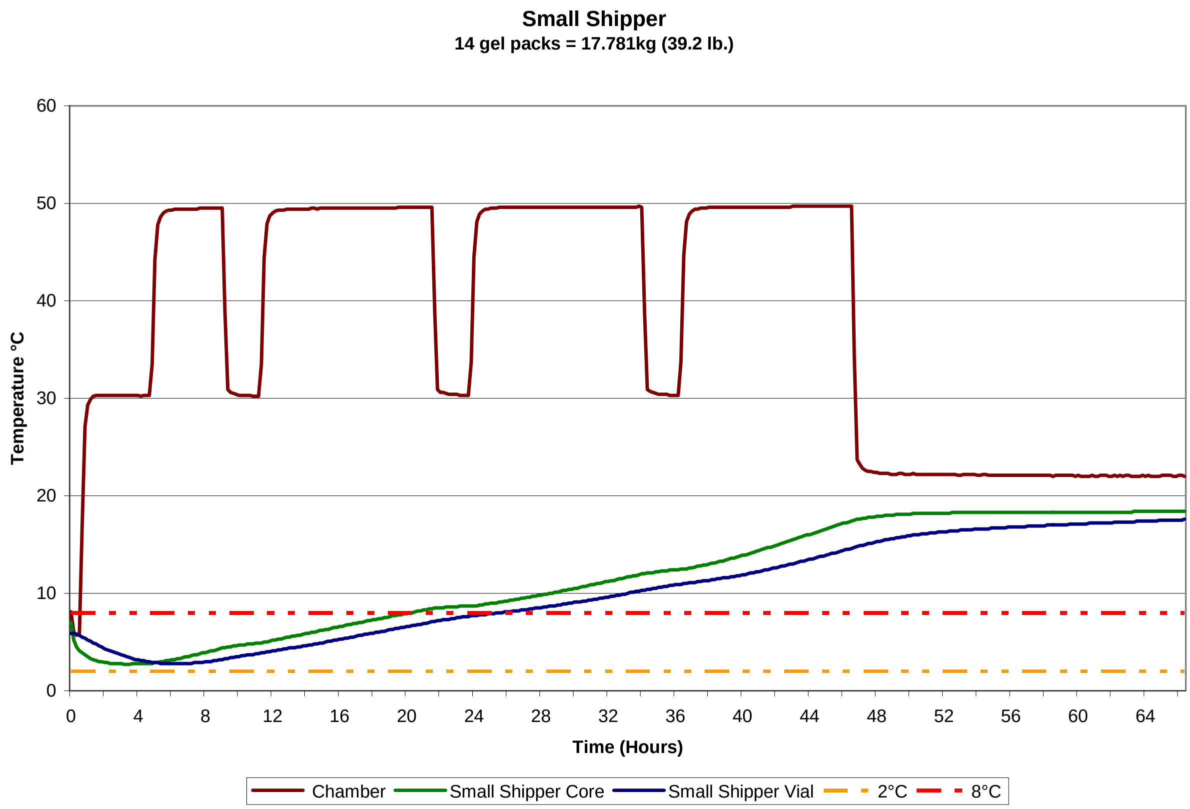


Figure 1
Unmodified ISTA 5B Profile and the Response of the Small Thermal Pack

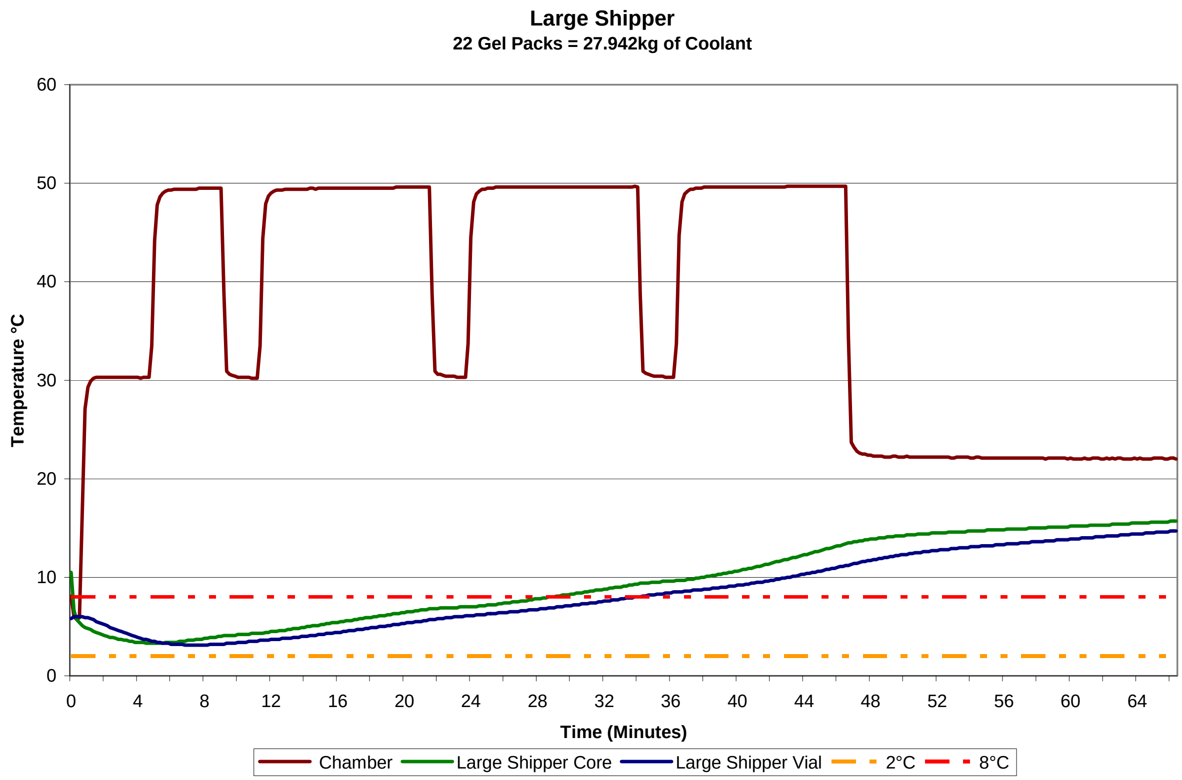


Figure 2
Unmodified ISTA 5B Profile and the Response of the Large Thermal Pack

Looking at the vial temperature in both package systems, the small thermal pack maintains +8°C for a little more than 24 hours and the large thermal pack maintains the +8°C for 34 hours. Neither package system makes it through the entire 48 hour profile. Please note that this is a representation of what may be an extreme profile of the distribution environment. Figure 3 represents the ISTA 7D Summer Profiles for 24 and 48 hour domestic shipment by air. Figure 4 represents a custom profile with the associated thermal data.

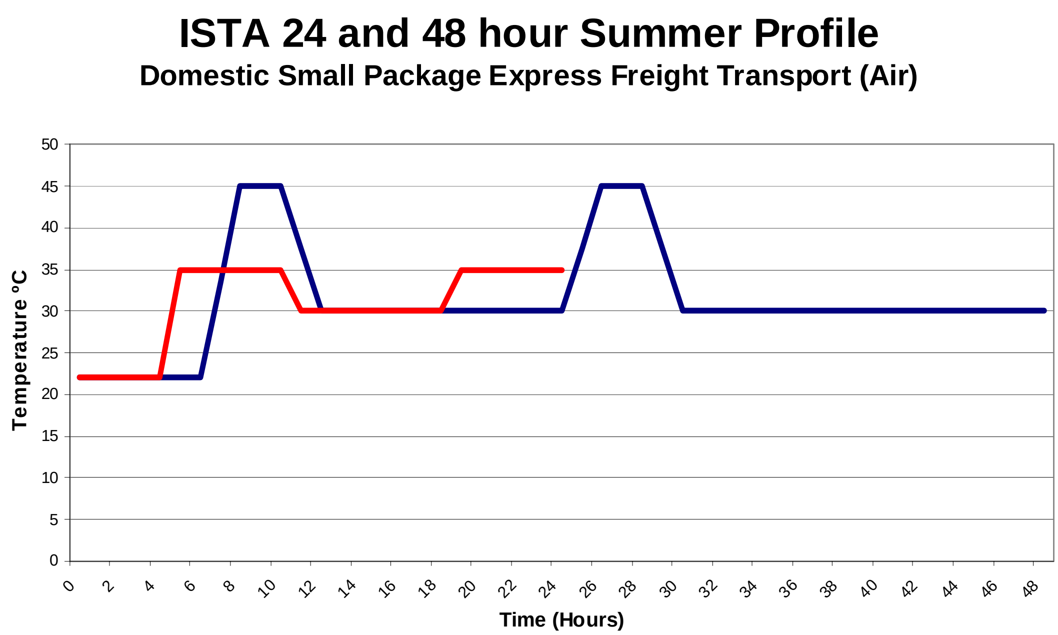


Figure 3
ISTA 7D Summer Profile

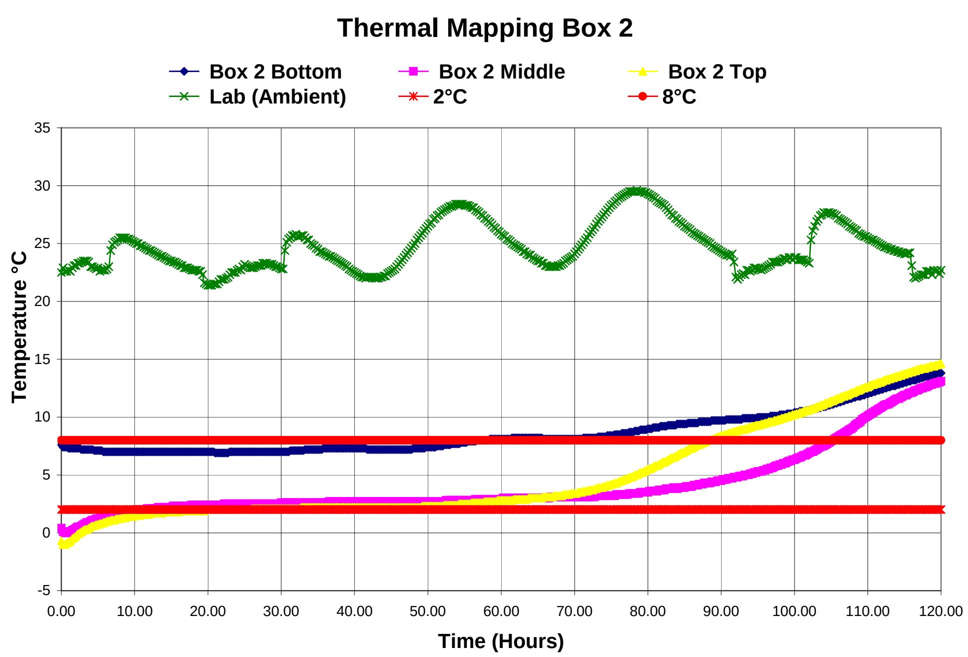


Figure 4
Custom Profile and Associated Response Data

Attention to detail is necessary when mounting temperature sensors and assembling the package system inside a test chamber. When a package system is subjected to a temperature profile the shipper comes out of the chamber in a pristine condition. Impacts or vibration have not had any effect on the system. When the package system is subjected to impacts and vibration the thermal characteristics of the package system can change dramatically. Cracked insulation will allow convection to occur at the damage site and reduce the ability of the package system to protect the product for the required duration. The coolant packs will also begin to melt; the plastic barrier may become torn or punctured no longer containing the gel. A routine distribution test may take only one day to complete, but the package system can become soggy and coolant packs can shift away from the product no longer providing adequate thermal protection. The ISTA 5B specification mentions that shock and vibration should be considered, however, it does not cover these inputs in any more detail.

A Simplified Method for Determining Thermal Resistance

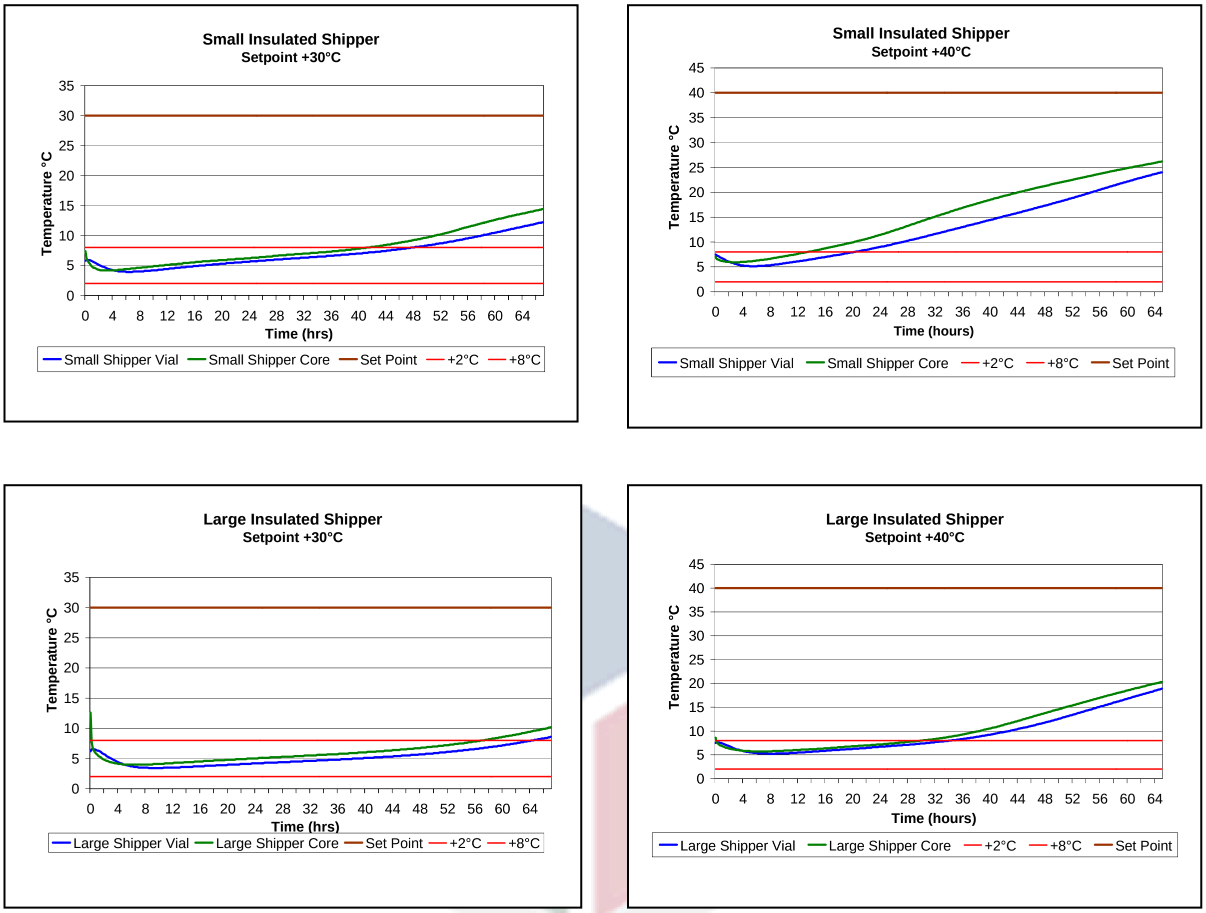
The information presented above discusses the many variables associated in thermal package design. However, what is really being discussed is the thermal resistance of the package system. Interestingly enough there are several assumptions made when developing a package system. The first is based on the thermal mass of the payload. Typical payloads consist of water and air therefore the thermal mass is relatively low. Products with a higher thermal mass will have a dramatic effect on the cooling capacity of the thermal package system. Next is the capacity of the coolant to remove heat from the product for the required duration. The coolant temperature is below our temperature range so the coolant continues to try to remove more heat to achieve 0C equilibrium. This concept is why we would want to have a phase change material at the required temperature range of +2 to +8°C.

Selecting the insulating properties of the material is critical in order to slow the transfer of heat to the product. Two off the shelf thermal packs were purchased constructed with 2 inch thick Expanded Polystyrene (EPS) insulating material. The table below summarizes the characteristics of both shippers. In addition, gel coolant packs were used both frozen and unfrozen. Care was taken to keep the core together. Locations were monitored at the vial and core of the package system using a data logger with RTD sensors which yields accuracy of +/- 0.2°C. Readings were taken every 10 minutes which allows for good resolution of temperature changes inside the package.

Shipper	Flute Type	Insulation Material	Thickness (in)	Shipper ID (in.)	Payload Box ID (in.)	Payload OD (in.)
Large	C flute	EPS	2	25 x 16 x 17.5	18 x 8 x 6	6.25 x 4.5 x 3
Small	C flute	EPS	2	16 x 16 x 19	9 x 7 x 7	6.25 x 4.5 x 3

The package system should be packaged so that the payload and the surrounding coolant are the same temperature (+2 to +8°C) and frozen coolant is insulated from the pay load so as not to make direct contact with the product. Additional frozen coolant shall be added if necessary surrounding the refrigerated gel packs. Expose the package to a high temperature or low temperature extremes and terminate the test once equilibrium is attained. Repeat for at least one other setpoint and compare the variation in slope. The data can then be used to create a model for the thermal performance of the package system. Since the internal components are the same, the internal cooling capacity of the system remains the same so the variables are reduced to the steady state temperature of the chamber. Selecting at least two setpoints around the highest temperature extreme will give you the ability to screen the thermal performance of a package before spending a lot of time testing each package system through an entire thermal profile. Figure 5 below shows an example of the package system tested at +30°C and +40°C.

Figure 5
Thermal performance of the small and large shippers



Conclusion

To summarize the above information, identify the duration of your distribution environment, 48, 72, 96 hours and the temperature extreme of the distribution environment by measurement or literature search. Calculate the thermal mass of the entire core to be cooled inside the package system. Pack-out the package system to eliminate shifting of the coolant during transport. Monitor several locations throughout the package system with a data logger. Select four temperatures (two high and two low) for the setpoint temperature to use in the steady state models to determine the thermal resistance of the package system. Conduct four tests one at each setpoint until the package system attains equilibrium. Calculating the thermal performance using this method may be refined to become a tool to eliminate the trial and error design of thermal packaging. A software model could be developed to predict the thermal performance of a single parcel shipment based on gel pack size, insulation properties, and product contents.

References

Huang, Francis F. “Engineering Thermodynamics Fundamentals and Application” Second Edition, Macmillan Publishing Company 1988 USA

“ISTA Guide 5B 2002 - 2007, Focused Simulation Guide for Thermal Performance Testing of Temperature Controlled Transport Packaging”, International Safe Transit Association, 1400 Abbott Rd., Suite 160, East Lansing, MI, 48823 USA

“ISTA Procedure 7D 2006 – 2007, Thermal Controlled Transport Packaging for Parcel Delivery System Shipment”, International Safe Transit Association, 1400 Abbott Rd., Suite 160, East Lansing, MI, 48823 USA

Schueneman, Herbert, H. CP-P/MH, “Design and Testing of Insulated Shipping Containers” Westpak, Inc., 83 Great Oaks Blvd San Jose CA 95115

Temperature Data gathered from the Washington Post Website, Natilan Weather Service in San Francisco CA