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Designing for Cold Chain – what is needed

Abstract: Newcomers to Cold Chain Distribution (shipping products cold) may be surprised that more “standardized” information is not available in the public domain. The intent of this paper is to identify areas of research which would benefit the industry and motivate companies to share their research and findings to benefit the industry. It is believed that once this key information is available and considered a foundational base – packaging suppliers and companies will then be able to develop more effective standardized packaging solutions for cold chain distribution reducing financial and environmental impacts. It is not the intent of this paper to address qualification protocol, procedures, or processes needed to meet government regulations such as required in the pharmaceutical industry.

Introduction

- What is Cold Chain Distribution?
- What are we trying to solve?
- What are the costs (financial and environmental) associated with poor design?
- Basics elements of Insulated Shippers and their variables
- Who is involved and what is research being done?
- Case studies

What is Cold Chain Distribution?

Cold chain distribution is a temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range.

Cold chain distribution is common in the food and pharmaceutical industries. It can also be found in some chemical shipments. A common temperature range for a cold chain distribution in pharmaceutical industries is 2 to 8 °C. The specific time at temperature tolerances depend on the actual product being shipped.[1]

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What are we trying to solve?

The key purpose in designing a container for cold chain shipment is to ensure that the product temperature stays within the proper temperature range for the entire duration of its trip from company to customer. The elements that allow for a successful design are various and can be interdependent, making design decisions difficult. Each of these elements has their own variables which can have an influence on the overall performance. Understanding each of these elements and the affect their variables have on the overall performance is critical to designing an efficient/effective cold chain container. The intent of this paper is to identify these elements and their possible variables, so then further research can be conducted in mapping out these influences and aiding the design process. It is also the intent of this paper to encourage packaging professionals & researchers, which have already conducted research in these areas, to come forward with their information to reduce redundant research and improve the industry as a whole.

What are the costs associated with poor cold chain design?

Human factors - Temperature sensitive products that stray outside their recommended temperature range might impact patient safety or compromise research results due to product alterations. This deterioration in product quality and patient safety can lead to a withdrawal or government recall of the product and thus to product loss. It can also lead to company liability and loss of brand equity when doubts are raised with regard to product quality and safety after temperature deviations. In regulated industries, such as pharmaceutical, the fines and penalties imposed can be severe.

Financial factors – Typical cost consideration focuses on container and coolant. However, a larger financial factor that is significantly impacted by poor design is logistics spend. Having a container that is too large costs more to ship (note: most cold chain shipment travel by the most expensive route – next day express air) and use more coolant than required. However, a container that cannot maintain the proper temperature range can compromise product quality> This can require replacement and incure all the cost of the initial shipment plus product loss, not to mention the additional cost of replacement product, another container with coolant, and re-shipping fees.

Environmental factors – Growing concerns around global warming and excessive packaging waste has driven sourcing decisions by customers. They now must consider the environmental impact of the cold chain containers they use. Impacts of poor design (ex. A large container holding a very small product) can be:

- Amount of container materials needing to be recycled or disposed of. In many cases, recycling may not be an option as the products being shipped go into laboratories which deal with biological materials and the packaging waste is not recycled.
- Amount of fossil fuel used to move the goods and it contribution to green house gases. Small containers allow more packages to travel in the same vessel at the same time, reducing the overall impact.

Basic elements of Insulated Shippers and their variables:

The design of Insulated Shippers essentially focused around controlling heat transfer by one or all of the following means: conduction, convection, and radiation.

Typically, heat transfer control is accomplished via thermal insulation and heat exchangers. Other methods and devices can also be incorporated depending on the solution utilized.

The calculation of heat transfer into an insulated container can be expressed as:

$$\mathbf{Q} = n \times L = A\,(T_0 - T_b)/R$$

Where:
n = rate at which the coolant melts (e.g. lb/hr)
L = latent heat of coolant (e.g. Dry Ice = 246 BTU/lb)
A = area of container walls
T_0 = coolant temperature
T_b = temperature outside the container
R = resistance to heat flow (R-value)

- Container
  - Material
    - R-Value - Type of material is normally selected in cold chain design based on cost and thermal performance. Thermal performance is typically referred to as "R value." The term R-value is predominantly used in the building industry to rate the insulative properties of construction materials and building assemblies. The higher the R-value, the greater insulation value.

      The relationship between R-value and thickness is not always exactly linear and therefore its value cannot be precisely extrapolated for a material of different thickness, but assuming a linear relationship is often adequate. In any case, R-values of adjacent materials can be added to determine a final R-value of the entire construction assembly; e.g., R-value(brick) + R-value(fibreglass batt) + R-value(plasterboard) = R value(total)

      The SI unit for R-value is $K \cdot m^2/W$.

      The imperial unit for R-value is $ft^2 \cdot °F \cdot h/Btu$. The conversion factor is 1 $ft^2 \cdot °F \cdot h/Btu \approx 0.1761\ K \cdot m^2/W$, or 1 $K \cdot m^2/W \approx 5.67446\ ft^2 \cdot °F \cdot h/Btu$.

      Sometimes the nomenclature 'RSI' is used to denote the SI form of the value. In contrast, the imperial unit is often written as R–31.4. To complicate matters, some countries that employ the SI system (e.g. New Zealand) retain the R but incorporate a dash e.g. R–5.53. One tenth of an RSI is called a tog.

      The R-value used to describe thermal insulating products includes heat being transferred by all three mechanisms -- conduction, radiation, and convection. The term used in the thermal insulation community is 'apparent thermal conductivity.' A formal definition for apparent thermal conductivity is contained in document C168 published by the American Society for Testing and Materials. The term is applied to situations involving the simultaneous flow of heat by all three transport mechanisms. The statement 'R-values are measures of conductive thermal resistance' is incorrect, if it implies a limitation, since 'R-value' includes radiation and convection when they are present."

      R-value should also not be confused with the intrinsic property of thermal resistivity and its inverse, thermal conductivity. The SI unit of thermal resistivity is $K \cdot m/W$. Thermal conductivity assumes that the heat transfer of the material is linearly related to its thickness.

      Typical R-values per inch of thickness - The Federal Trade Commission (FTC)'s R-value Rule generally prohibits calculating R-value per inch of thickness. (16 C.F.R. 460.20.) The FTC explained the reason for this prohibition: Since the record demonstrates that R-values are not linear, advertisements, labels, and other promotional materials that express a product's thermal resistance in terms of R-value per inch deceive customers. The FTC further explained that references to the R-value for a one-inch thickness of the material will encourage consumers to think that it is appropriate to multiply this figure by the desired number of inches, as though R-value per inch were constant. (44 Fed Reg. at 50,224 (27 August 1979).)

All values are approximations, based on the average of the values listed on dozens of websites. Furthermore, comparisons per inch of thickness are mostly relevant for conductive and convective heat transfer -- not radiant heat transfer -- but some of the materials listed below are designed to prevent radiant heat transfer.

- Cellulose loose-fill = R-3 to R-3.8.
- Molded expanded polystyrene (EPS) = 3.7 for low-density, 4 for high-density.
- Extruded expanded polystyrene (XPS) = 3.6 to 4.7 for low-density, 5 to 5.4 for high-density.
- Open-cell polyurethane spray foam = R-3.6.
- Closed-cell polyurethane spray foam = R-5.5 to R-6.5.
- Polyurethane rigid panel (Pentane expanded)= 6.8 initial, 5.5 aged (5-10 years).
- Polyurethane rigid panel (CFC/HCFC expanded)= 7 to 8 initial, 6.25 aged (5-10 years).
- Foil-backed bubble pack = R-1 to R-2 (as per industry testing, despite manufacturers' claims)
- Vacuum insulated panel = as high as R-30?
- Cardboard = R-3 to R-4

K-value or the measure of thermal conductivity can also be used to benchmark insulated container design. K-value is calculated by dividing the R-value by the insulation thickness.

  - Example: High R-Value = Low conductivity

☼ *What is needed: More research/information on performance of current cold chain packaging materials.*

Density

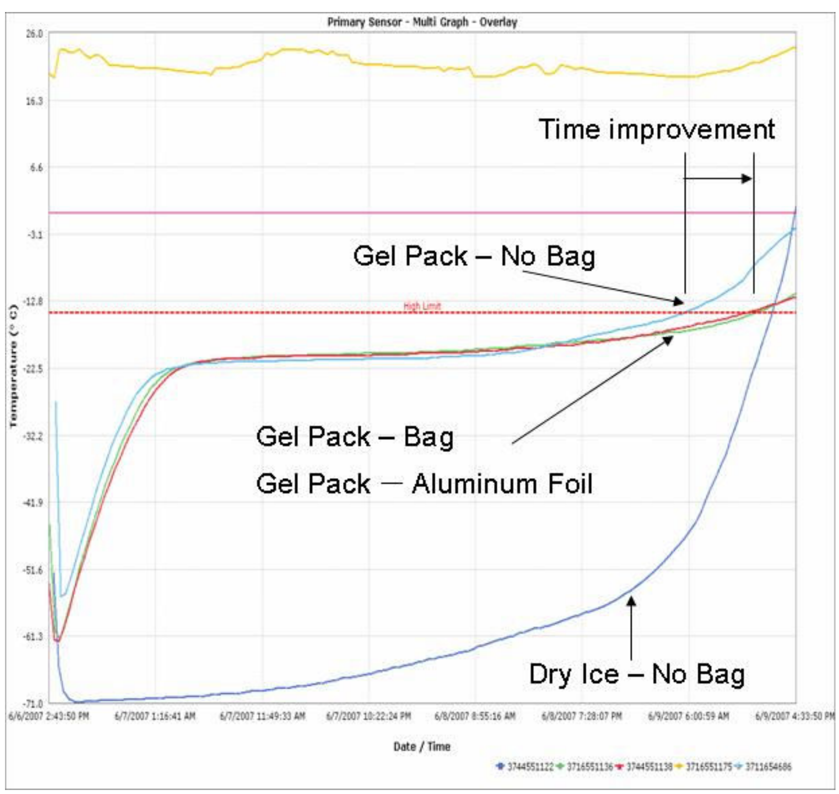
Measurement of density - For a homogeneous object, the formula mass/volume may be used. The mass is normally measured with an appropriate scale; the volume may be measured directly (from the geometry of the object) or by the displacement of a liquid. A very common instrument for the direct measurement of the density of a liquid is the hydrometer.

In cold chain design, density has a direct relationship to the R value of the container. However, little public research has been made available that shows the correlation of density to time duration performance. The results of an unconfirmed study was shared that indicated, for EPS foam, insulative performance increase as density increases up to 1.5 lbs/cu.ft.

then the performances drops off compared to the additional density.
☼ *What is needed: More research/information on the differences in density for a given thickness vs. duration performance.*

- Wall thickness
  - Simply put – the thicker the wall the greater thermal performance and it is what R value is based on. A test comparing two different company containers (Case Study 1 - Invitrogen vs. Omaha Steaks) which had the same outside cubic dimension but different wall thickness showed a significant performance difference. The container with the thicker wall lasted 2 times longer that the thinner walled container but had half the payload capacity. The cold chain industry typically ships express air, so every cubic inch is expensive (performance vs. payload).
    ☼ *What is needed: More research/information on the differences in wall thickness vs. duration performance of various material types. This should show when additional thickness adds little additional value.*

- Films
  - Use of metalized wraps and aluminum foil have been shown to increase the insulative properties duration time. Below is the result of one test performed at Applied Biosystems to test the concept. The metalized wrap acts primarily as a radiant barrier and also, but less effectively limits convection. Thus, the use of this device may be more effective as a radiant barrier in less insulative packages (EPS) and more of a convection barrier in greater insulative packages (PU). Additional research is needed to document predictive vs. actual increased duration performance.



☼ *What is needed: More research/information on duration performance of various film material types..*

- Lid closure design
    - Sealing properties (tongue and groove) – double tongue and grove has been claimed to be better than single tongue and grove as it creates resistance to air flow.
    - Mechanical hold (friction, tape, shrink band) – Bellows effect
    - Has the greatest effect on dry ice or frozen shipments where the denser cold air is more likely to escape through seems and openings.

    ☼ *What is needed: More research/information on the differences in closure designs vs. duration performance.*

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- Size
    - Payload area
    - Surface area

    ☼ *What is needed: More research/information on the differences in Payload and surface area vs. duration performance and coolant usage.*

* Refrigerant (Cooling Engine)
    - Dry Ice - Greatest amount of thermal energy absorbed.
    - Phase Change – Engineered gel absorbs specific amount of thermal energy.
    - Frozen Gel (0 degree) – Becomes frozen when stored at 0 degrees Celsius.
    - Melt index / Sublimation
        - Time – based on amount – more mass the better
        - Size (cubic area)
        - Density

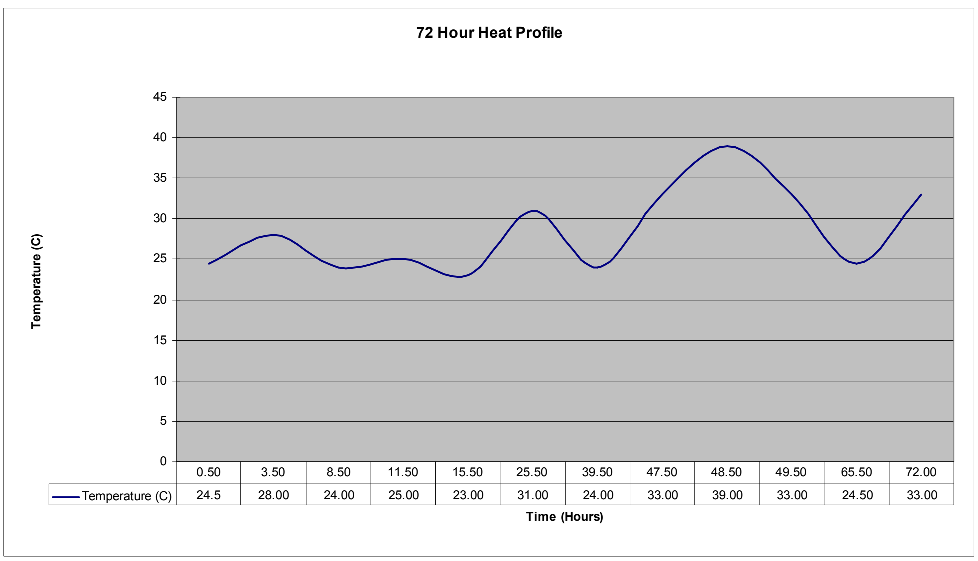
    ☼ *What is needed: More research/information on the differences in coolants vs. duration performance and amount of coolant usage.*

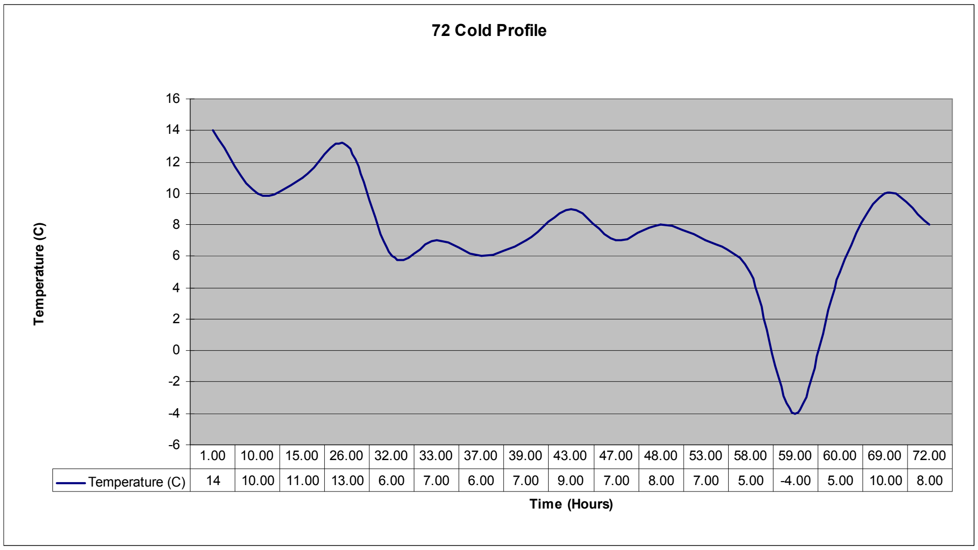
* Ambient Temperature
    - Public profiles – Amgen, ISTA 5B
    - Highs
    - Lows
    - Cycles
    - Seasonal
    - Statistical Significance (e.g. FDA) and correlation (NASA, USGS)

    ☼ *What is needed: More public domain information on ambient temperature measurements, profiles in use, and reposts of successful applications.*

Example of profile shared by Amgen at ISTA technical conference

Geographical Area of Shipping Lanes Represented Within the Amgen Heat and Cold Profiles





- Payload
  - Mass (thermal mass)
  - Size (cubic area)
  - Temperature range/tolerance
  - Characteristics (stability/excursions)

  ☼ *What is needed: More research/information on the differences in product characteristics vs. impact on duration performance and amount of coolant usage.*

- Shipment Time
  - Length of time in between pack-out and receipt (transit)

  ☼ *What is needed: More public domain information on transit times for different levels of carrier services and lanes. This will help to better establish validation testing and amount of coolant usage.*

Who is involved and what is research being done

There are a number of packaging professionals, consultants, and university professors involved in research around cold chain elements. It would be difficult, if not impossible, to identify them all in this paper but I will mention a few organizations that I'm aware of below. I will post a more comprehensive list of those I'm aware of to my web site, www.talkpkg.com, and encourage others in this field of study to identify themselves so they to can be listed and the industry can have a central point of reference.

Organizations

- PDA – Pharmaceutical Cold Chain Interest Group (PCCIG) – www.pda.org
  - PDA Technical Report 39, Revised 2007 Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products Through the Transportation Environment University
- Cold Chain Committee (C3) - http://www.c3info.org/
- University of Florida – Jean-Pierre Emond (jpedmond@ufl.edu) http://cfdr.ifas.ufl.edu
  - Dr. JEAN-PIERRE EMOND,

- Professor, Packaging Science, ABE
- Co-Director, UF/IFAS Center for Food Distribution and Retailing
- 229 Frazier Rogers Hall
- Museum Road
- University of Florida
- Gainesville, FL 32611-0570
- (352) 392-1864 ext 229

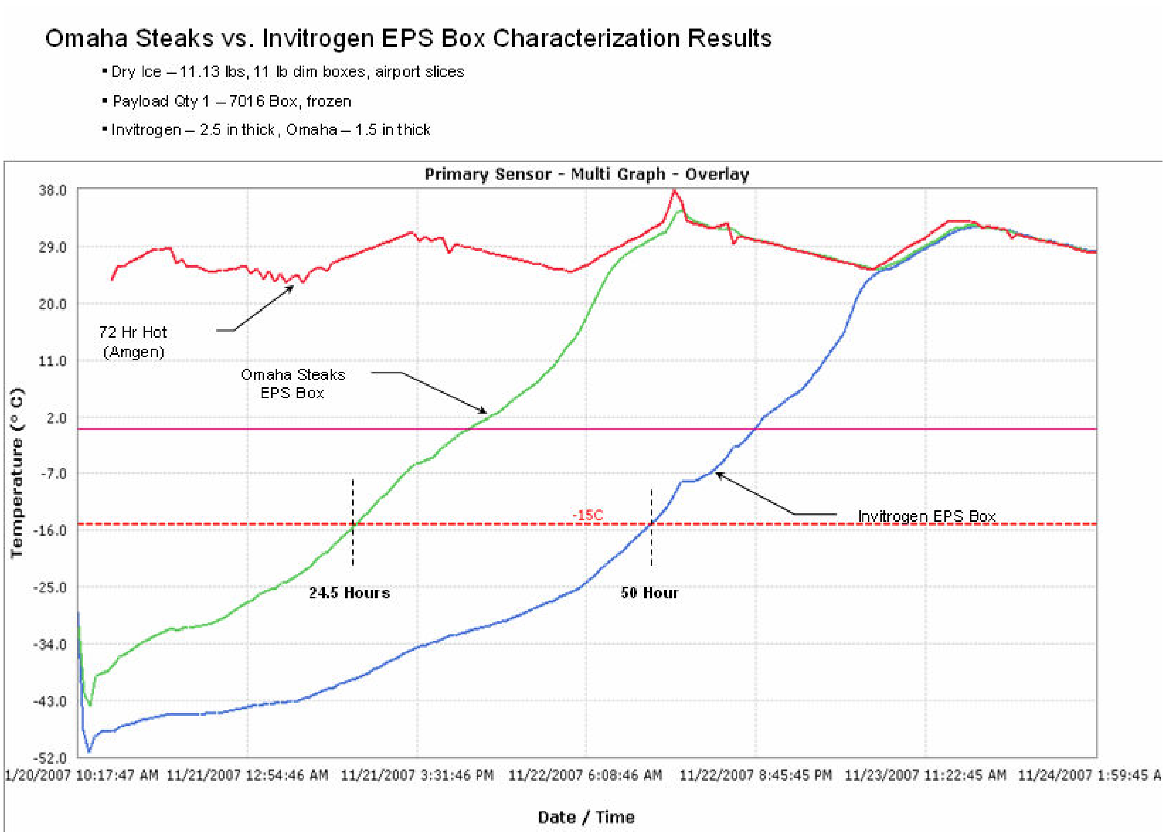
Web and Blogs

- Cooler Heads (http://www.coolerheadsblog.com/) - Hosted by Kevin O'Donnell, Technical Director at SCA Americas, ThermoSafe Brands
- Talkpkg.com (http://www.talkpkg.com) hosted by Paul Russell
- Answers.com (http://www.answers.com/topic/cold-chain?cat=health)
- Australia Cold Chain Center (http://www.coldchaincentre.com.au/)
- Cold Chain Management (http://www.iaph.uni-bonn.de/Coldchain/)
- Wi kipedia (http://en.wikipedia.org/wiki/Cold_chain)

Case Studies

In an effort to start the sharing of information, we have included some simple case studies (what if scenarios). It is our belief that others in our industry have conducted more thorough investigations in these areas.

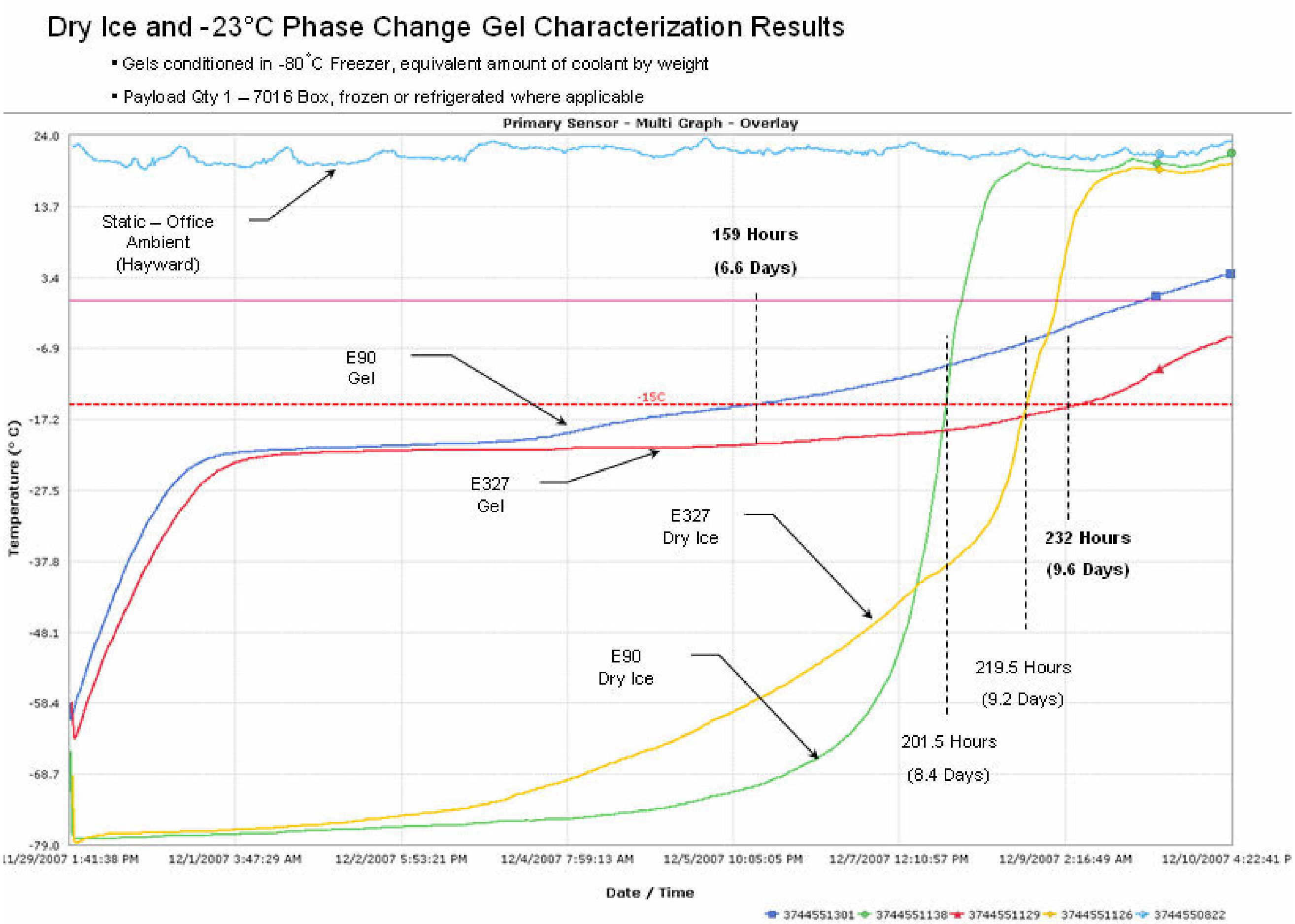
1. Invitrogen vs. Omaha Steaks
   - Same outside DIM (11.134)
   - One container had thinner walls and more payload space (47% more space)
   - Same amount of coolant (7 lbs of dry ice)



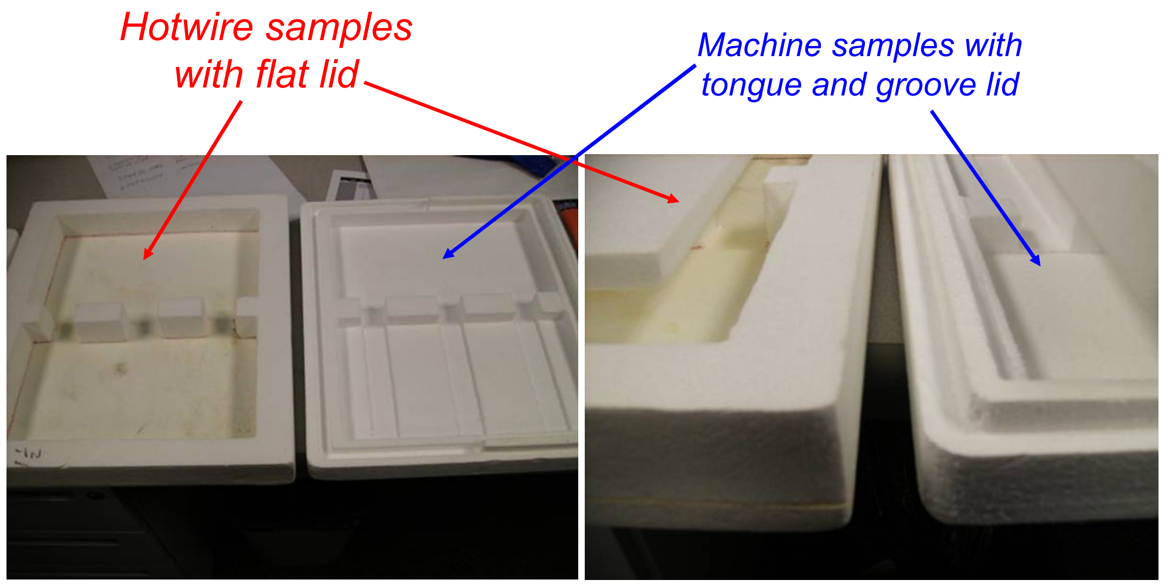
Invitrogen vs. Omaha Steaks

	Outside					Inside payload					wall	Hr	Hr	Hr	lowest
container	L	W	D	Cube	dim	L	W	D	Cube		thickness	below	below	below	temp
Omaha small	16	15	9	2160	11.13	12.3	11	4.75	625.5156	47%	1.5	27	21.5	24.5	-43
Invitrogen	15	12	12	2160	11.13	9.5	6.9	6.5	424.5313		2.375	52	47	50	-51
												93%	119%	104%	19%

2. -23 Phase Change Gel vs. equivalent amount of Dry Ice
    - E327 box with gels performed better than the dry ice sample



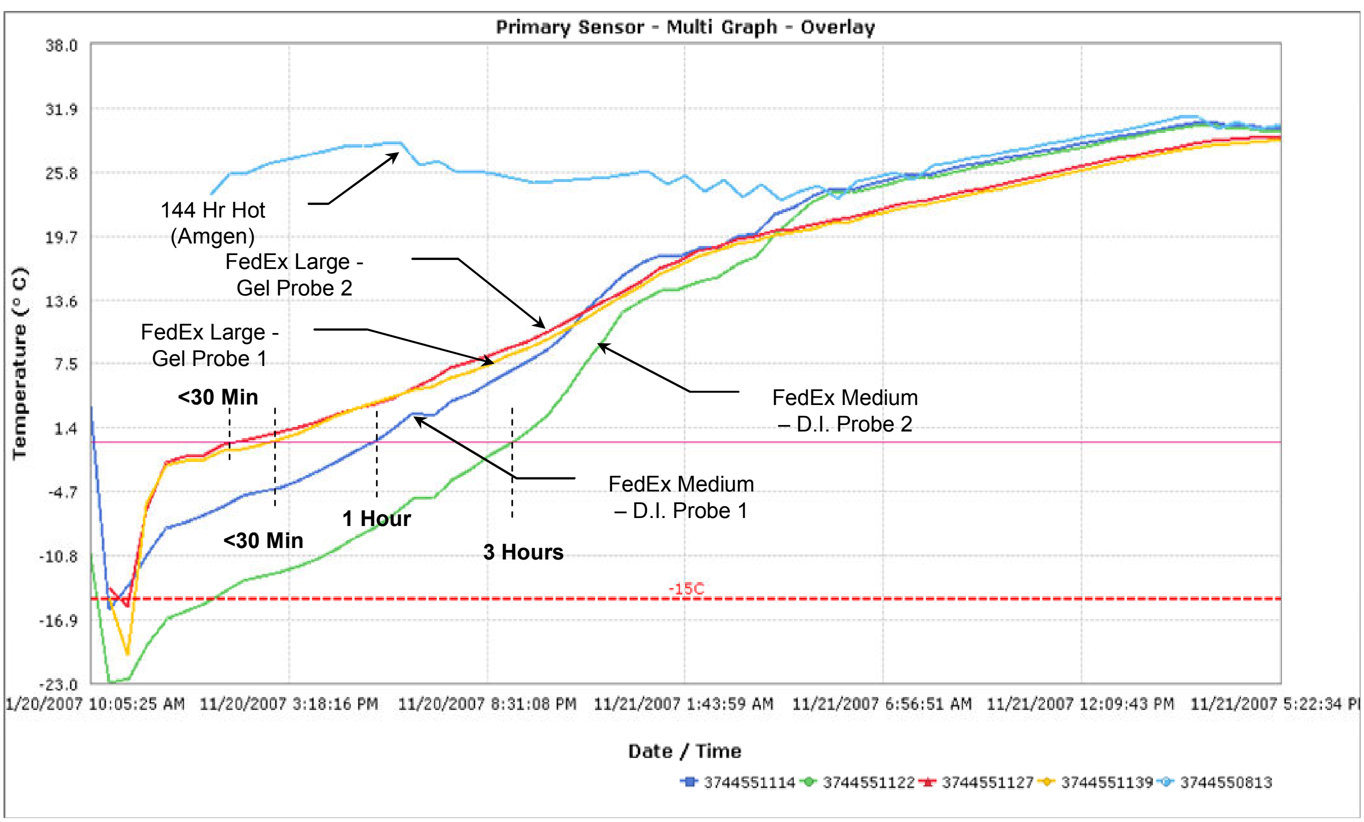
3. Express carrier concept boxes



Express Carrier Box Characterization Results

Hotwire samples with flat lid

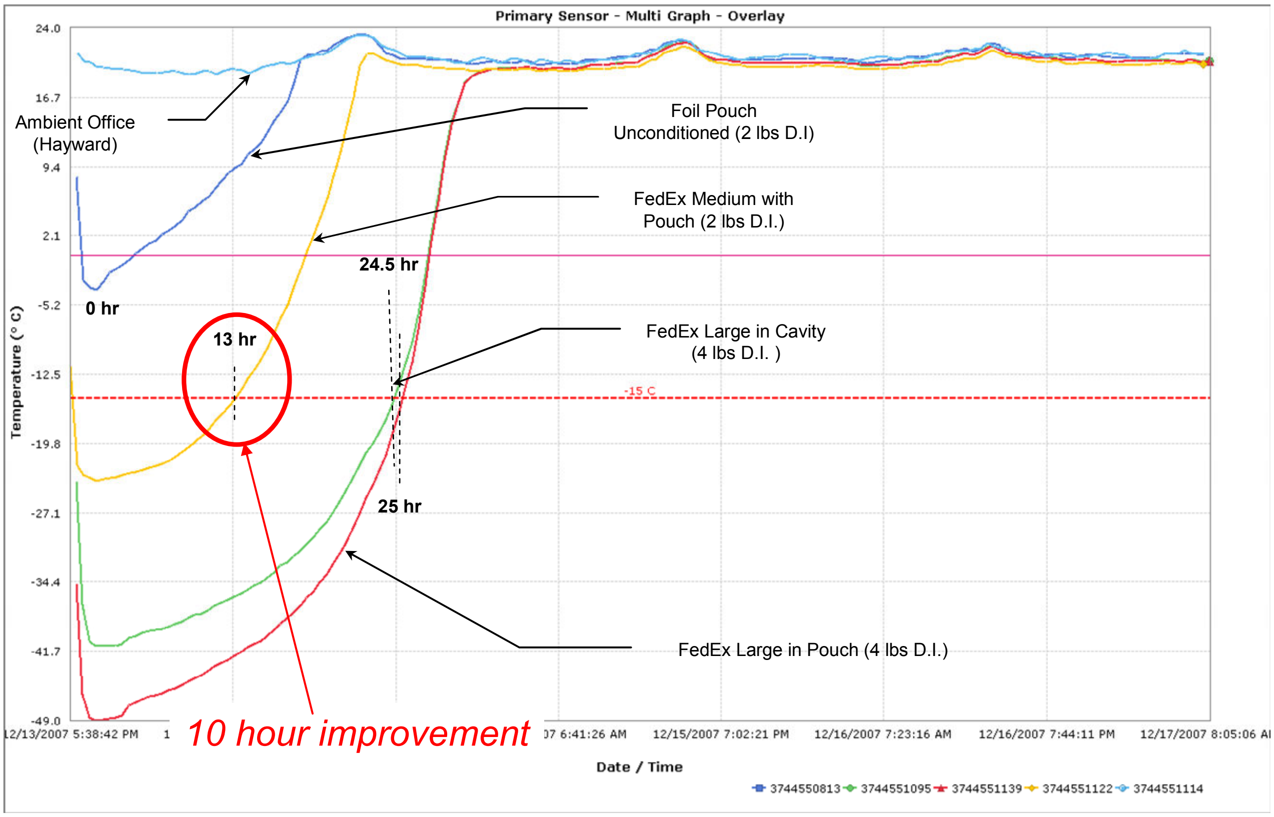
- Gels conditioned in -80°C Freezer,
- Payload Qty 1 – 7016 Box, frozen or refrigerated where applicable
- Custom hot wired EPS box placed inside stock shipping mailer, thermal wrap, thickness of less than 1 inch, no lid closing features



Express Carrier Box Dry Ice Characterization Results

Machine samples with tongue and groove lid

- Dry ice coolant
- Payload Qty 1 – 7016 Box, unconditioned
- Custom EPS box placed inside stock shipping mailer, EPS with tongue and groove closing features



References

[1] Wikipedia - Cold chain - http://en.wikipedia.org/wiki/Cold_chain