Temperature Controlled Packaging Container for Biologics and Pharmaceuticals

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Temperature Controlled Packaging Container for Biologics and Pharmaceuticals

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FINAL PROJECT REPORT
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EXECUTIVE SUMMARY

Clinical Supplies Management, Inc. (CSM) provides clinical trial services to biotechnology and pharmaceutical companies by shipping pharmaceuticals to clinics and other patients. In winter 2014, CSM presented a temperature control packaging project to the Cal Poly Senior Project class. As a result, three Cal Poly Mechanical Engineering Students were tasked to design, manufacture, and qualify a shipping container that would maintain ten 10 mL vials between 2-8°C for 96 hours. The final product would have to cost less to ship than the Credo Cube, CSM's current temperature control packaging product. After considerable research and analysis on possible temperature control technologies, it was determined that the most reliable and economical solution was similar technology to the Credo Cube.

The main features of the product are as follows:

1. Vacuum Insulated Paneling (VIP) is used as a thermal resistor to reduce the heat transfer from the surroundings to the payload
2. Phase change material (PCM) maintains the desired payload temperature

An optimization for the specified payload was performed by creating designs to reduce the tare weight, and dimensional weight using the above technologies.

During the manufacturing phase, the selected vendor for phase change material was unwilling to accommodate a lead time within the senior project's scope. This was believed to be partially due to the low volume and direct competition of the potential product. CSM was in contact with the vendor, and it was decided that the legal steps needed to move forward with the selected PCM would be too far outside of the project's scope. Consequently, it was decided between the project team and CSM that using water as a prototype PCM was acceptable. Instead of a final product, a proof of concept prototype and a calculator that would help CSM redesign the product if other VIP or PCM were to be pursued in the future acted as the final deliverables.

Although the prototype was not able to maintain temperature within range for 96 hours, the design can easily be scaled to do so with further testing and the use of the provided calculator.

The following report details the design, manufacture, and qualification of the shipping container prototype.

Chapter 1 INTRODUCTION

This report is a Cal Poly Mechanical Engineering Senior Design Final Report to be presented to the sponsor and Cal Poly Mechanical Engineering advisor. Three senior mechanical engineering students seek to address a problem that the project sponsor has identified in a yearlong capstone project.

1.1 Sponsor Background and Need

Clinical Supplies Management, Inc. (CSM) provides clinical trial services to biotechnology and pharmaceutical companies. It was founded in 1997 and changed the industry with its "On-Demand Packaging & Labeling" services, which shortened a company's clinical study timeline by two to four months ("About Us"). CSM also offers the follow packaging and labeling services:

- Returns, Reconciliation and Destruction
- Clinical Supplies Consulting
- Controlled Substance Handling
- Traditional Packaging and Labeling
- Storage and Global Distribution

CSM is the connection between pharmaceutical companies who manufacture the drug and the site that conducts the clinical trial. Because new medicines are increasingly temperature sensitive, shipping costs related to cold-chain technology is a rising concern at CSM. Due to the nature of clinical trials, only small volumes of biologics and pharmaceuticals are shipped to a client at a time. However, current temperature controlled packaging technology, namely the Credo Cube, is causing undesirable dimensional weight costs to CSM and the clinical trial site clients. Additionally, the temperature dependent biologics and pharmaceuticals go through a highly regulated process from the time it is manufactured to the time it is shipped to the customer. The current processes at CSM expose the temperature sensitive drugs to heat between sub-processes. The drugs are first placed in primary packaging, which is then placed in secondary packaging (namely cardboard cartons), and then placed back into the refrigerator until the tertiary and shipping packing are ready.

1.2 Formal Problem Definition

New medicines are increasingly temperature sensitive. After consideration of alternate methods, it has been determined that elevating root cause of this issue (the medicine is temperature dependent) is out of the scope of this project. The next best course of action to maintain temperatures of temperature sensitive medicines is to eliminate superfluous handling at the shipping and distribution level.

A new packaging product is needed to decrease the heat transfer between vials and the environment during this process. This product will increase the efficiency of the supply chain, and the quality of the pharmaceutical product increases in parallel.

Authors of this report (for the remainder of the report will be referred to as “the project team,” “the team,” or “MAC”) will work with the sponsor to design, develop and qualify a multiple-use temperature controlled packaging container for ten 10mL vials. The shipping container will replace the current secondary packaging of the vials, improve shipping and distribution processes, and decrease dimensional weight shipping costs.

While eliminating non-value-added shipping processes, this also reduces the risk of the medical products being exposed to heat in the environment, which increases quality of the product.

1.3 Objective/Specification Development

Engineering specifications were created using the House of Quality in the Quality Function Deployment Method. The House of Quality is a planning matrix that relates customer requirements to how the project team will meet these requirements. From this method, the team was able to identify that customers care about product safety, product ability to maintain temperature range for 72-96 hours and product ability to prevent breakage of vials as the highest priorities. These will be the driving design specifications throughout the development of the new packaging product. Reference Appendix A for completed House of Quality matrix.
The project sponsor has identified these requirements for the new packaging product:

- Protect 10 vials during shipment
- Maintain 2-8 degrees Celsius for 96
- Reduce shipping cost
- Be reusable
- Replace secondary packaging
- Be safe
- Have space for a temperature monitor
- Low handling time (pre-conditioning, maintenance)
- Match reliability rating of current standard of 100%
- Be low cost (dependent on reusability and pre-conditioning time)

Engineering specifications derived from sponsor requirements include:

Table 1: Engineering Specifications

Spec #	Parameter Description	Requirement	Tolerance	Risk[1]	Compliance[2]
1	Space for Vials	10 vials	Min	L	A, I
2	Internal Temperature Range	5 C	+/- 3 C	M	A, T
3	Maintaining Temperature Tmax	96 hours	Min	M	A, T
4	Vial Protection	0 Vials cracked after 10 foot drops (5)	--	L	T
5	Reusability	Maintains dimensions under tolerance with 100 lb. axial load applied for 72 hours	Min	M	T
6	Safety	No hazardous substances	--	M	T
7	Reliability	Products meet engineering requirements in 50/50 trials	Min	M	T
8	Robust	Maintains engineering requirements under air freight cargo environment (temperature, pressure, humidity)	--	M	T
9	Usability	Container can be opened in the same time as the Credo Cube	+ 10%	M	T
10	Space for Temperature Monitor	Container has space for 1 TempTale or 1 El Pro temperature monitor	Min	L	I
11	Quality Control	Temperature monitor remains functional after one shipment	--	L	T, I
12	Cost	Manufacturing costs do no exceed $400/container	Max	H	A

[1] Risk of not meeting specifications: High (H), Medium (M) or Low (L)

[2] Methods to ensure product compliance to requirement include: Analysis (A), Test (T), Similarity to Existing Designs (S), Inspection (I)

Each specification is also rated for risk and compliance. Risk indicates the feasibility of the specification where a High Risk specification has the lowest feasibility. Specification 12 is dependent on project technology and is the only specification rated as High Risk. However, it is a driving design specification and will be address as outlined in subsection "Method of Approach."

The compliance rating of each specification is simply the method of verification or how the team will evaluate the product meeting specification after each design prototype. While there are four methods that are generally utilized to verify compliance, the team has rated each specification with numerical analysis, test and visual inspection. Any results will be recorded to present to the sponsor and general audiences.

1.4 Project Management

Each member will be involved in all aspects of the design. However, lead roles are defined to create accountability through the process. Roles of the project team are defined as follows:

Melinda
- Primary Contact with Sponsor
- Lead CAD Modeler
- Lead Test Developer and Execution

Yufay
- Lead Heat Transfer Analyst
- Lead Prototype Manufacturer

Abraham
- Treasurer
- Secretary
- Lead Contact with Vendors
- Lead Product Assembler

The team meets at a minimum for 9 hours a week, 6 of which are scheduled lab hours. A complete Gantt chart of all tasks can be found in Appendix F.

Chapter 2 BACKGROUND

Several areas of background research were performed to fully understand and define the problem. Areas of research include insight into Cold Chain technology, current temperature control technology, regulations on medical substances and the further background on the sponsor.

2.1 Industry Need and Relevance

According to Dr. Ravi Prakash Mathur, director of Supply Chain Management for Dr. Reddy's Laboratories, in the next six years patents on high volume, high revenue drugs generating $267 billion in sales will expire (Chrzan 2013). More sophisticated, personalized drugs are currently on clinical trial and will soon take over the market. In fact, the Cold Chain Biopharma Logistics Sourcebook 2011 predicts that world sales of temperature-sensitive drugs and of biologics such as vaccines and blood plasma products will near $250 billion by 2015 (Bates 2012). Large shares of pharmaceutical and medicinal shipments are classified as chilled products, which mean they must be stored in a temperature range between 2 and 8°C (Rodrigue 2013). Pharmaceuticals and biologics are susceptible to damage during shipment and storage, and every delay between the times of manufacture of the medicine to the time it reaches the patient can have negative consequences. The more that products have to change hands in the supply chain, the higher the chance for temperature excursions and compromised products.

2.2 Additional Sponsor Background

CSM currently goes through a meticulous process from receiving the product from pharmaceutical companies to product shipment to the clinical trial site. Reference Figure 1 below for the overall process.

The pharmaceutical product goes through receiving, inspection, inventory, processing and finally shipping and distribution.

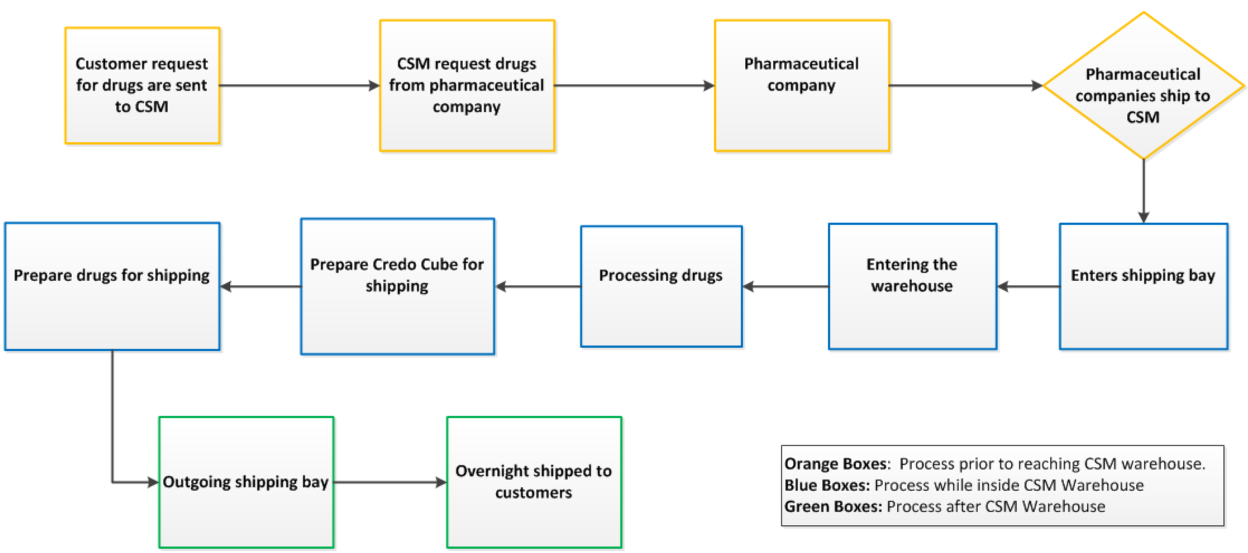


Figure 1: CSM process

Products arrive from pharmaceutical companies, products return from customers and reusable packaging returns arrive at CSM shipping dock (sally port style). Pharmaceutical products arrive in refrigerated trucks and are briefly inspected before the truck departs.

Products are then 100% inspected in controlled temperature before inventoried in warehouse. Returned reusable shipping containers are cleaned during inspection as well.

Products are stored and monitored in the warehouse until processing. Ranges of temperature dependent products are kept in several refrigerators equipped with continuous monitors (resolution of one degree Celsius). Temperature control packaging is also stored in the warehouse. Preconditioning of phase change material in temperature control packaging occurs at this point of the process, at most for 36 hours.

Processing includes clinical label printing, labeling of the product and kitting of product. In On-Demand processing, drugs are also reconstituted by a pharmacist or pharmacist technician. Drugs are placed into the primary packaging (i.e. a bottle), labeled, placed in secondary packaging (i.e. a cardboard box with many bottles), and placed in a plastic bag. After kitting, temperature dependent drugs go back into the refrigerator to await documentation signage.

After preparing documents and temperature controlled packaging (from the refrigerator in the warehouse to shipping), the drugs are taken from the warehouse and kitted inside the Credo Cube. The cube is placed in a corrugated shipping box, sealed and labelled. The product waits for at most a day in the outgoing shipping bay in which time the temperature controlled packaging has started its 96-hour cycle.

2.3 Existing Products

Temperature controlled shipping containers are used for transporting thermally sensitive products. This can range from frozen produce to live pets. Whatever the purpose, there is a need to maintain a shipping container cold or warm in some cases.

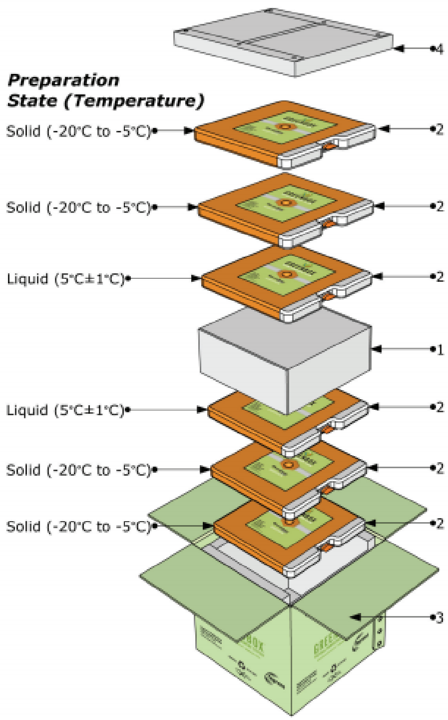
2.3.1 Industry Leader - Credo Cube

The current product used by CSM to transport thermally sensitive pharmaceutical products is the Credo Cube, shown in Figure 2. It is capable of maintaining temperatures between 2-8°C for up to four days at ambient temperatures ranging from 22-35°C. The Credo Cube is kept at these low temperatures with 6 phase change material filled panels (phase change occurs at 5°C) that are surrounded by 6 vacuum insulated panels. Vacuum insulated panels provide the best insulation where only one mode of heat transfer through the panels: radiation. This combination of insulation and refrigerant makes the Credo Cube fairly lightweight and minimizes volume compared to its competitors.

Figure 2: Credo Cube Exploded View

2.3.2 Green Box

One of Credo Cube's leading competitors is the Green Box. This alternative provides much smaller payload volumes than the Credo Cube. The Green Box uses 4 panels of phase change materials and 2 panels of refrigerated liquid. In the same sizing, the Green Box is slightly heavier than the Credo Cube. Figure 3 shows the configuration of the Green Box and the order of each refrigerant.



Bill of Materials			
Item	Qty.	Part No.	Description
1	1	24DPC	Payload Box
2	6	B38A	10" ThermoPhase™ 4 (orange) panel
3	1	P29R	Green MDPE Corrugated Outer
4	6	V428	Vacuum Insulation Panel

Step	Action	Ref.
1	Open the flaps of the green MDPE corrugated outer container and remove the top vacuum insulation panel. Ensure the shipper is empty; if not, remove all components except for the five (5) remaining vacuum insulation panels.	3,4
2	Place two (2) solid 10" ThermoPhase™ 4 (orange) panels in the bottom of the shipping container.	2
3	Place one (1) liquid 10" ThermoPhase™ 4 (orange) panel directly on top of the previously placed solid panels.	2
4	Position temperature-sensitive payload in payload box. Add paper dunnage around payload in payload box to provide physical damage protection. Place closed payload box directly on top of the previously placed panel .	1
5	Place one (1) liquid 10" ThermoPhase™ 4 (orange) panel directly on top of the payload box.	2
6	Place two (2) solid 10" ThermoPhase™ 4 (orange) panels in the shipping container directly on top of previously placed liquid anel.	2
7	Replace top horizontal vacuum insulation panel with seam facing up, then close top of the shipper.	3,4
8	Tape top of the shipper appropriately	

Figure 3: GreenBox

2.3.3 Other Competitors

Other competitors' performances are summarized in Figure 4 below. Data was gathered from Cal Poly College of Business Packaging Department peer-reviewed publications.

The shape of the gel packs plays a significant role. With large surface and small volume, gel packs melt faster but keep the product cooler and with small surface and large volume, the gel packs last longer but the product is not as cold (Sighn).

In Dr Sighn's research, wall thickness, not considering the recycled content EPS containers, was observed to be directly proportional to the observed R-values. Considering the containers with 2.54 cm thick walls, those with VIP performed 128% and 267% better than the polyurethaneand virgin EPS, respectively. For the two containers studied with 5.08 cm thick walls, containers with polyurethane performed approximately 77% better than those made with virgin EPS. When comparing the R-values against recycled content,containers with 90% recycled content had the highest value of 14.5. The 80% and 100% recycled content containers displayed 5.80% and 6.28% lower R-values, respectively, as compared with the 90% recycled content containers.

Package	Insulated container systems	Average R-values ($m^{2\circ}C/W$) 24 h
1a	C-Flute corrugated fibreboard box with 19 mm EPS foam panels	1.66
1b	C-Flute corrugated fibreboard box with 13 mm EPS foam panels	1.63
2	C-Flute corrugated fibreboard box	1.05*
3	Oyster ThermalCor® box	1.25*
4	ThermalCor® box with ThermalCor® tube	1.41
5	Foil ThermalCor® box	1.69
6	Foil ThermalCor® box with 4.8 mm inch foil bag insert	1.91
7	EPS container with lid	2.00
8	Polyurethane foam moulded container	2.56
9	ThermalCor® box in a ThermalCor® box	1.29
10	Foil-laminated ThermalCor® box in a ThermalCor® box	1.73
11	ThermalCor® box in a foil-laminated ThermalCor® box	1.48
12	Foil-laminated ThermalCor® box in a foil-laminated ThermalCor® box	1.73

*Tested for 12 h.

Figure 4: Summary of Commercial Product R-Values (Sighn, 2008)

By material type, the R-value-based performance of the containers can be ranked in a decreasing order as vacuum-insulated panels, polyurethane, recycled content EPS and virgin EPS. Wall thickness, not considering the recycled content EPS samples, was observed to be directly proportional to the observed R-values. Considering the containers with 2.54 cm thick walls, those with VIP performed 128% and 267% better than the polyurethane and virgin EPS, respectively. For the two containers studied with 5.08 cm thick walls, containers with polyurethane performed approximately 77% better than those made with virgin EPS. Recycled content EPS containers outperformed the virgin EPS containers for all densities and thicknesses studied

Only approximately 20% of the containers tested were able to maintain the temperature of the product at 2 C– 8 C for more than 24 hours. The regression results suggest that, in isolation, the R-value and wall thickness variables are significant at a 5% level, where the R-value exerted a positive influence and wall thickness a negative influence.

Product name	Type	Weight (g)	Size L × W × D (cm)	Melting point (°C)	Latent heat (kJ/kg)
Polar Pack	GP	680	22.2 × 14.6 × 3.8	−1.1	314
Utek #597	PCM	454	16.5 × 16.5 × 2.2	−4.5	395
Ice Brix	GP	680	20.3 × 15.2 × 3.2	0.6	349
Johnny Plastic XC48Y	PCM	1190	27.3 × 15.2 × 4.4	−5.6	418
Kool-It Bricks	GP	680	12.7 × 12.7 × 4.4	0	356
Cold-Ice	GP	454	17.8 × 15.2 × 2.5	1.7	349
P-S Hot-Cold	GP	680	21.6 × 21.6 × 2.5	−2.2	344
Guardian PCM4C	PCM	454	22.9 × 7.6 × 2.5	3.3	353
Re-Freez-R-Brix	GP	908	22.9 × 10.2 × 3.8	−0.6	339
Vaxi-Safe PCM	PCM	454	22.9 × 8.3 × 2.5	3.9	314
Cryopak	GP	680	41.9 × 30.5 × 1.9	0	337
Teap TH7-PCM	PCM	340	15.2 × 10.2 × 3.8	7.2	383

Figure 5: Summary of Commercial Product Latent Heat (Sighn, 2008)

It was found to be optimal to use low wall thickness except when it was accompanied by high R-values. (Singh)

2.3.4 Relevant Patents

There are many patents that currently exist pertaining to temperature controlled shipping containers. A majority of the patents are generally the same; they consist of some sort of insulated outer layer, along with a refrigerant inside. One patent that is interesting to note is # US 8,613,202 B2, see Figure 6. Uniquely configured, this container only has a pack of refrigerant on top of the payload, item #40 in Figure 6. With space around the payload for airflow, heat naturally rises and causes the air to be cooled by the refrigerant. Other relevant patents are listed in Table 2.

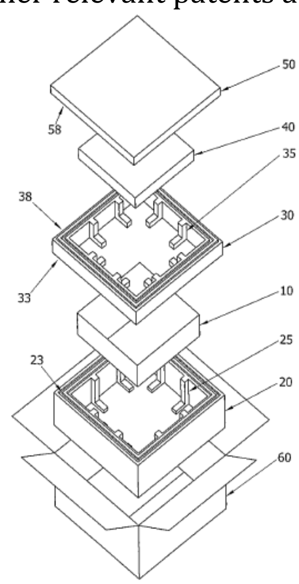


Figure 6: Patent # US 8.613.202.B2 Exploded View of the Shipping Container (Insulated Shipping Container Systems and Methods Therof. Allan Williams, assignee. Patent 8,613,202. 24 Dec. 2013. Print.)

Table 2: Related Patents for Temperature Controlled Shipping Containers

Patent Number	Description	Publication Date
US 8,613,202 B2	Container with an insulated outer layer that provides space for airflow with only one pack of refrigerant on the topside of the payload.	June 17, 2010
US 8,250,882 B2	Container with insulation on the outer layer with space in the insulation for coolant bricks. The payload has a 45C temperature gradient from the exterior.	March 26, 2009
US 7,849,708 B2	Insulated container with the payload surrounded by a phase change material or refrigerated gel packs.	Aug 21, 2008
US 5,924,302	The container has a rigid structure surrounding the thin sheets of insulating material with slots for the lid to create a better seal. The empty space is then filled in with foam.	July 20, 1999

2.4 Current State of the Art

While there has been in an increase in temperature sensitive drugs, there has been a complex supply chain in place for other temperature sensitive products such as food. According to a 2013 article in The Geography of Transport Systems, the Cold Chain is defined as “the transportation of temperature sensitive products along a supply chain through thermal and refrigerated packaging methods and the logistical planning to protect the integrity of these shipments” (Rodrigue, 2013). Perishable or temperature sensitive products transported in the Cold Chain are called Cool Cargo. More recently, the Cold Chain is also referred to as the Cool Chain in European Temperature Controlled Logistics communities. This logistics system that provides a series of facilities for maintaining ideal storage conditions for perishables from the point of origin to the point of consumption utilizes several different technologies including:

Table 3: Common Cold Chain Technology

Technology	Description	Photo Example
Dry ice	Solid carbon dioxide, is about -80°C and is capable of keeping a shipment frozen for an extended period of time. It is particularly used for the shipping of pharmaceuticals, dangerous goods and foodstuffs and in refrigerated unit load devices for air cargo. Dry ice does not melt, instead it sublimates when it comes in contact with air.	 (Wikipedia contributors. "Dry ice." *Wikipedia, The Free Encyclopedia*. Wikipedia, The Free Encyclopedia, 2 Dec. 2014. Web. 5 Dec. 2014.)
Gel Packs	Packages that contain phase change materials to maintain a temperature. Depending on the shipping requirements, these packs can either start off in a frozen or refrigerated state. Along the transit process they melt to liquids, while at the same time capturing escaping energy and maintaining an internal temperature.	 (Wikipedia contributors. "Phase-change material." *Wikipedia, The Free Encyclopedia*. Wikipedia, The Free Encyclopedia, 18 Nov. 2014. Web. 5 Dec. 2014.)
Eutectic plates	The principle is similar to gel packs. Instead, plates are filled with a liquid and can be reused many times.	 ("Plaques Eutectiques." Accynykateyrs De Friud. N.p., n.d. Web. 04 Dec. 2014.)

Technology	Description	Photo Example
Liquid NO2	An especially cold substance, of about - 196°C, used to keep packages frozen over a long period of time. Mainly used to transport biological cargo such as tissues and organs. It is considered as a hazardous substance for the purpose of transportation.	 (Wikipedia contributors. "Nitrogen." *Wikipedia, The Free Encyclopedia*. Wikipedia, The Free Encyclopedia, 3 Dec. 2014. Web. 5 Dec. 2014.)
Quilts	Insulated pieces that are placed over or around freight to act as buffer in temperature variations and to maintain the temperature relatively constant. Quilts can also be used to keep temperature sensitive freight at room temperature while outside conditions can substantially vary (e.g. during the summer or the winter).	 ("PalletQuilt®." Our PalletQuilts® Cover Any Size Pallet, Tote, Drums, ULD or Combo Load!! N.p., n.d. Web. 04 Dec. 2014.)
Reefers	Generic name for a temperature controlled transport unit, which can be a van, small truck, a semi-trailer or a standard ISO container. These units, which are insulated, are specially designed to allow temperature controlled air circulation maintained by an attached and independent refrigeration plant. The term reefer increasingly applies to refrigerated forty foot ISO containers with the dominant size being 40 high-cube footers.	 ("Best Refrigerated Shipping by The Cold Box™." N.p., n.d. Web. 04 Dec. 2014.)

According to Dr. Jay Sighn, Director of the Cal Poly Packaging Department, “Cold chain solutions typically involve excessive packaging to ensure that the desired product temperature is maintained through distribution, thereby increasing the logistics-related costs. Those costs are estimated to be six times that of the package itself” (Singh, 2013).

2.4.1 Methods of Temperature Control

2.4.1.1 Phase Change Material

A phase change material is a substance with a high heat of fusion. It is a substance that is used to control a constant temperature while it is changing phase. Most industry leaders utilize some form of phase change material in their temperature controlled packaging.

2.4.1.1.1 Water and Gel Packs

Ice and gel packs are useful for keeping materials cold around 0°C. These substances have the advantages of good performance, low cost, nontoxic, not flammable, environmentally friendly and easy to use. The only disadvantage to these ice and gel packs is that they are only useful at maintaining their surroundings or thermal load at 0°C. To obtain a water-based PCM lower than 0°C, a salt can be added to the water. This will depress the freezing point. However, this significantly decreases the latent heat and broadens the melt/freeze temperature.

2.4.1.1.2 Salt Hydrates

Salt hydrates are the lowest cost PCM followed by water and gel packs. The material comprises M•nH2O, where M is an inorganic compound.

Salt hydrates have limited temperature ranges available to salts in meeting specific temperature needs at the desired temperature. Few salts melt between 1 and 150°C. In the absence of salts melting at temperatures between 1 and 150°C, eutectic mixtures and salt hydrates are pursued for these missing temperature ranges. Most salt hydrates melt incongruently (e.g., they melt to a saturated aqueous phase and a solid phase, which is generally of a lower hydrate of the same salts. Due to density differences, the salt phase settles out and collects at the bottom of the container, a phenomenon called decomposition (phamoutsourcing.com, 2014).

Another common problem found in salt hydrates is with the salt hydrates' poor nucleating properties that result in super cooling of the liquid salt hydrate prior to freezing. This must be overcome by the addition of a suitable nucleating agent that has a crystal structure similar to that of the parent substance.

Other issues of using salt hydrates involve the volume change, the corrosive nature of the salt hydrate and the toxicity of some of these materials. The volume change in the solid/liquid phase change of a salt hydrate can be up to 10%. This can be accommodated for by using special packaging. The packaging needs to be specific to the type of salt hydrate used. Many salt hydrates are corrosive to metals. The toxicity of salt hydrates also varies widely.

2.4.1.1.3 Paraffins

Paraffins are high-molecular-mass hydrocarbons with a waxy consistency at room temperature. Paraffins are made up of straight chain hydrocarbons. The melting point of paraffins is directly related to the number of carbon atoms within the material structure with alkanes containing 12-40 C-atoms possessing melting points between 6 and 80 degrees C. Paraffin waxes contain a mixture of hydrocarbon molecules with various carbon numbers with lower melting points and poorer latent heats than pure paraffins. Paraffin waxes are often considered a low-grade PCM ("Phase Change Materials .

Paraffins have good thermal storage capacity and can freeze without super cooling. Paraffins also have the advantages of chemical stability over many heating and freezing cycles, high heat of fusion, they are non-corrosive, compatible with most all materials and non-reactive to most materials of encapsulation.

Commercially cost-effective paraffins are mixtures of alkanes and therefore do not have sharp, well-defined melting points. Wax products are commercially viable for a variety of applications including uses in canning and candle making. A C20-C24 canning wax has a latent heat of 150 J/g and melts over a 7°C temperature range— considerably poorer performance than +98% n-paraffin products found in most literature. Pure paraffins are also limited in their range of melting points that they can achieve ("Phase Change Materials…").

2.4.1.1.4 Vegetable-based PCMs

The safety, environmental and social benefits of using vegetable-based PCMs are significantly greater than those of paraffins. Many vegetable-based PCMs can be considered, "food grade". Researchers under the Department of Agriculture research program discovered that many vegetable-based PCMs had lower flash points and 10-20% longer horizontal flame propagation rates than did their temperature-comparable, paraffin-based counterparts. Many vegetable-based PCMs can be derived locally using common agricultural crops. ("Phase Change Materials…"). Table 4 provides a comparison of Vegetable-Bases PCMs from Entropy Solutions.

Table 4: Comparison of PCMs ("Pure Temp," 2014)

	PURETEMP	PARAFFIN	WATER BASED	SALT HYDRATES
SOURCE	VEGETABLE	PETROLEUM	WATER	MINERALS
AVERAGE LATENT HEAT	170 – 270 j/g	130 – 170 j/g	330 j/g	140 – 170 j/g
TEMP OPTIONS	200+	LIMITED	LIMITED	LIMITED
TEMP RANGE	-40 C – 150 C	-8 C – 22 C	0 C	15 C – 80 C
TOXICITY	NON-TOXIC	MID	NON-TOXIC	MID-HIGH
ENCAPSULATION	YES	YES	NO	NO
FLAMMABILITY	LOW	HIGH	NONE	NONE
STABILITY	UNLIMITED	UNLIMITED	UNLIMITED	UNLIMITED
RENEWABLE	YES	NO	YES	NO
BIODEGRADABLE	6 MONTH	100 YEARS	N/A	N/A

2.4.1.1.5 Encapsulation Methods of PCM

Encapsulation of phase change material is necessary in order to prevent the evaporation and leakage when it is a liquid. Micro-encapsulation is the process of placing PCM in a polymer shell that has a core size from 10 to 1000 microns, shown in Figure 7. Macro-encapsulation is contained in a polymer shell that has a core size greater than 1000 microns. (Pure Temp Technology)

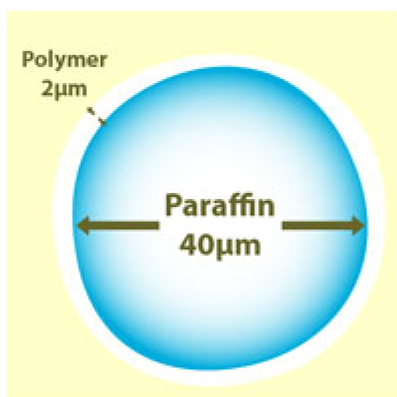


Figure 7: Micro-Encapsulation ("Pure Temp," 2014)

2.4.2 Thermoelectric Cooling

Thermoelectric cooling is also known as Peltier cooling, named after the inventor, Jean Charles Anthanase Peltier. This system functions by applying current to the n-type semiconductors which are connected with p-type semiconductors in parallel ("Thermoelectric Cooler Basics"). Ceramic plates are used to sandwich the semiconductors since ceramic is an excellent heat conductor. The n-type semiconductors produce a cooled surface while the p-type semiconductors produce a hot surface. In order to dissipate the heat from the hot surface, a heat sink is installed, see Figure 8.

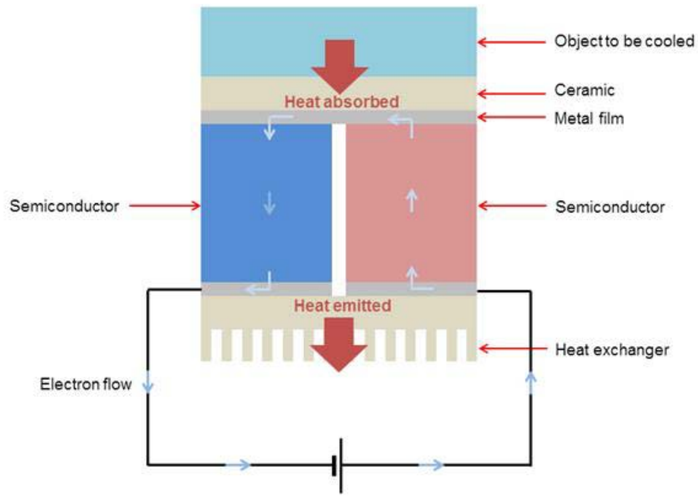


Figure 8: Typical Thermoelectric Cooling Couple

Although the coefficient of performance in thermoelectric systems is low, it is more practical to use as opposed to a refrigeration cycle when size is a significant factor. Parts are more cost effective for a small thermoelectric system than a small refrigerator. The coefficient of performance is calculated from a simple equation; the amount of heat absorbed on the cold side divided by the electrical power provided. Generally the coefficient of performance for smaller applications similar to this project is less than one. To put this in perspective, good refrigerators can have coefficient of performances as high as 4 (Incropera). That means the heat absorbed in the thermoelectric system can be four times the power provided.

Batteries can run a thermoelectric system. Thermoelectric systems can draw as little as a fraction of a watt to over 1000 watts. Standard batteries run at 12 VDC or 24 VDC and come in a large variety of sizes.

Thermoelectric plates are inexpensive and are reliable. Commercial thermoelectric coolers can last over 250,000 hours, approximately 28 years ("Thermoelectric Cooler Basics").

2.4.3 Thermal Insulation

Thermal insulation is the reduction of heat transfer between two objects with a thermal gradient. Insulation is measured by the R-value which is the ratio of temperature difference across insulation and the heat flux. Materials with high R-values are very good thermal insulators and reduce the heat transfer between two objects.

The unit of thermal resistance is the R-value.

$$R = \frac{L}{k}\left(\frac{m^2K}{W}\right)$$
$$L = \text{thickness}(m)$$
$$k = \text{thermal conductivity}\ \left(\frac{W}{mK}\right)$$

Table 5: List of Thermal Insulators ranging from high to low thermal resistances

Material	m²·K/(W·in)	ft²·°F·h/(BTU·in)
Vacuum insulated panel	5.28–8.8	R-30–R-50
Silica aerogel	1.76	R-10
Polyurethane rigid panel (CFC/HCFC expanded) initial	1.23–1.41	R-7–R-8
Polyurethane rigid panel (CFC/HCFC expanded) aged 5–10 years	1.10	R-6.25
Polyurethane rigid panel (pentane expanded) initial	1.20	R-6.8
Polyurethane rigid panel (pentane expanded) aged 5–10 years	0.97	R-5.5

Vacuum Insulated panels have the highest R-values ranging from 30-50 ft2·°F·h/(BTU·in). Followed by aerogels with a R-value of 10 ft2·°F·h/(BTU·in). As a result, vacuum insulated panels and aerogels are the two most common types of thermal insulation used for temperature sensitive applications.

2.4.3.1 Vacuum Insulated Panels

In commonly used insulation materials i.e. fiberglass and glass wool the main method of heat transfer is through convection in the gas between the pores. By reducing the amount of gas between the pores, a lower thermal conductivity can be achieved.

The gas conductivity in a porous medium is determined by the number of gas molecules as transfer medium as well as by the number of "walls" on the way from the hot to the cold side.

Gaseous conductivity is also determined by the thermal conductivity of the non-convective gas. Reducing the gas pressure by "evacuation (vacuuming the gasses out)", the gaseous conductivity remains almost unaffected until the mean free path attains values that are in the order of the size of the (largest) pores or higher. Pressed powder boards made of fumed silica with the largest pores in the same order of magnitude as the mean free path of air molecules at atmospheric pressure (about 70 nm) can achieve this (Simmler).

Vacuum technology can be used to inhibit all heat transfer mechanisms. The "ultimate" example of vacuum insulation is the Dewar's Flask, commonly known as a "Thermos bottle". In a Dewar's Flask the space between the dual walls of a cylinder is completely (99.999999%) evacuated. With virtually no molecules of gas available heat transfer by conduction and convection are almost eliminated and therefore thermal conductivities are extremely low –0.00576 W/mK (R 250) or better ("Vacuum Insulation Panel Technology"). Nevertheless, it is mechanically difficult to support such a pressure differential between the outside and inside of the flask. This certainly limits the structural configurations and the choice of materials for fabrication. Addition ally, since even a few molecules of gas will destroy its insulation value, the cylinder walls must be impermeable to gas and moisture. In addition, because radiation travels best through a vacuum where there is nothing to hinder its path the wall materials are limited to either specially treated glass or metal, both have a tendency to conduct consider able amounts of heat at areas where the walls are joined together.

In Johansson, PÄR's publication, "Vacuum Insulation Panels in Buildings", he listed the cost of VIP was £70/m/^2(EUR 84 per m2) for the 10 mm thick VIP and £80/m2 (EUR 96 per m2) for the other thicknesses. The cost in terms of USD is $97/10.76 ft2, which is $9/ft2. In a report prepared by NAHB Research Center, Inc. for the U.S. Department of Housing and Urban Development Office of Policy Development and Research, the listed cost of one square foot of 1" thick finished VIP using INSTILL Core was $4-7/ft2 (Johansson).

Thermal resistance per unit price is much less than conventional materials. They are more difficult to manufacture than polyurethane foams or mineral wools, and strict quality control of manufacture of the membranes and sealing joins is important if a panel is to maintain its vacuum over a long period. Air will gradually enter the panel, and as the pressure of the panel normalizes with its surrounding air, its R-value deteriorates. Conventional insulation does not depend on the evacuation of air for its thermal performance, and is therefore not susceptible to this form of deterioration ("Vacuum Insulated Panel".)
In addition, VIP products cannot be cut to fit as with conventional insulation, as this would destroy the vacuum, and VIPs in non-standard sizes must be made to order, which also increases the cost (NAHB).

The core material suitable for VIP production has to fulfill different requirements: small pore diameter, open cell structure, resistance to compression (atmospheric pressure) and impermeable to infrared radiation.

To reduce the gas conductivity in normal insulation materials the pressure has to be very low which is difficult to maintain by an envelope made of organic materials. A combination of nano-structured core material and pressure reduction is used.

To be able to evacuate the core material, it has to be open-celled, and then the gas (air) can quickly be removed from the material.

The internal pressure of a VIP is only few mbar. Consequently, the pressure load on the panel is close to 1 bar or 10 tons/m2. The core material therefore has to be stable enough so that the pores do not collapse when evacuated.

Besides gas conductivity, radiation has also to be reduced to reach very low conductivity values. This is done by adding opacifiers to the core material. Opacifiers are either effective IR photon scatterers or absorbers in the infrared region. The latter absorb IR radiation photons emitting from a hot surface and re-radiate them isotropically in all directions ("Radiation Contribution"). This is a very effective mechanism at frustrating heat flow toward the cold side of an insulation system.

Today different organic and inorganic insulation materials with open-cell structure are available for the use as core for VIP-production corresponding to the pore size distribution, the solid conductivity and the radiation properties of a material, a specific heat conductivity results, depending on the gas pressure.

A combination of fibers is mixed into a batch, and called a core. This core is enclosed by a fleece bag and is pressed into the shape of a board. The board is cut to desired dimensions and is placed in a barrier bag. The bag is vacuumed and sealed. As long as there is a vacuum in the barrier bag, the vacuum insulated panel will retain its low thermal conductivity (Thorsell).

Table 6 displays a list of vendors and product thermal values.

Table 6: Available Vendors and Product Ratings

Company	R-Value
Panasonic	R-60
Dow Corning	R-9.8
Thermocore	None listed
KevoThermal	R-12
Porextherm	R-30

Note that R-Values are dependent on the thickness of the insulation where

$$R = \frac{thickness}{thermal\ conductivity}$$

2.4.3.2 Aerogel

Aerogels are good thermal insulators since they nullify convection and conduction. They are good conductive insulators because they are composed almost entirely from a gas, and gases are very poor heat conductors. Silica aerogel is especially good because silica is also a poor conductor. Air being unable to circulate though the

lattice structure causes it to be a satisfactory convective inhibitor. Aerogels are poor radiation insulators because infrared radiation (which transfers heat) passes right through silica aerogel.
The high potential of silica aerogels is due to their unusual solid material properties. Silica aerogels consist of a cross-linked internal structure of SiO2 chains with a large number of air-filled pores. These pores of aerogel are very small: pure aerogel has an average pore diameter between 10 and 100 nm, but silica aerogels in general will have pore sizes between 5 and 70 nm, depending on the purity and the fabrication method, which will take from 85 up to 99.8% of the total aerogel volume (Baetens).

Due to its extraordinary small pore sizes and high porosity, the aerogel achieves its physical, thermal, optical and acoustical properties, while on the other hand this also results in a very low mechanical strength. The high porosity makes aerogels the lightest solid material known now. It has a density of approximately 2200 kg/m3, but the high porosity can result in a bulk density as low as 3 kg/m3, while current aerogels for building applications have an overall density of 70–150 kg/m3 (Baetens).

The process starts with a liquid alcohol such as ethanol, which is mixed with a silicon alkoxide precursor. A hydrolysis reaction forms particles of silicon dioxide forming a sol solution. The oxide suspension begins to undergo condensation reactions which result in the creation of metal oxide bridges linking the dispersed colloidal particles. When this interlinking has stopped the flow of liquid within the material, this is known as a gel. Acidic or basic catalysts are used to improve the speed.

The gel is pressurized and heated past its critical point, when it is a gas and liquid. The gas is depressurized while it is above critical temperature. As the pressure decreases, molecules are released as gas and the fluid becomes less dense. The gel is removed from the heat source. After the structure cools, there is too little alcohol to recondense back into liquid, so it reverts to a gas. The remnant is a solid made of silica, but now filled with gas (air) where there was once liquid. ("Insulation Products").

Aerogels have a low thermal conductivity resulting from a low solid conductivity, a low gaseous conductivity and a low radiation infrared transmission. The gaseous thermal conductivity can be reduced (i) by filling the aerogel with a low-conductive gas (e.g. noble gases), (ii) by decreasing the maximum pore size or (iii) by applying a vacuum on the aerogel. An overall thermal conductivity of 8 mW/(m K) can be reached for silica aerogels by applying a pressure of 50 mbar or less, if no further attempts are made to decrease the radiation transfer.

The overall thermal conductivity at ambient pressure can be decreased to a value of 13.5 mW/(m K) at ambient pressure and to 4 mW/(m K) at a pressure of 50 mbar or less, whereas state-of-the-art commercially available aerogel insulation for building purposes has a thermal conductivity between 13.1 and 13.6 mW/(m K) at ambient temperature ("Spaceloft is Manufactured by Aspen Aerogels").

Table 7 displays available vendors, rated thermal properties and prices.

Table 7: Comparison of Aerogel R-Values and Cost

Company	Thermal Conductivity	Price
Cabot: Thermal Wrap	23 mW m^{-1} K^{-1}	$33.33/$ft^2$
Spaceloft	14 mW m^{-1} K^{-1}	$30.00/$ft^2$
Cryogel	14 mW m^{-1} K^{-1}	$30.00/$ft^3$
Aspen Aerogels	13.8 mW m^{-1} K^{-1}	Must Contact
Spaceloft	14 mW m^{-1} K^{-1}	$5.00

2.5 Other Relevant Technical Data

2.5.1 Heat Transfer Modes

The three modes of heat transfer are conduction, convection, and radiation.

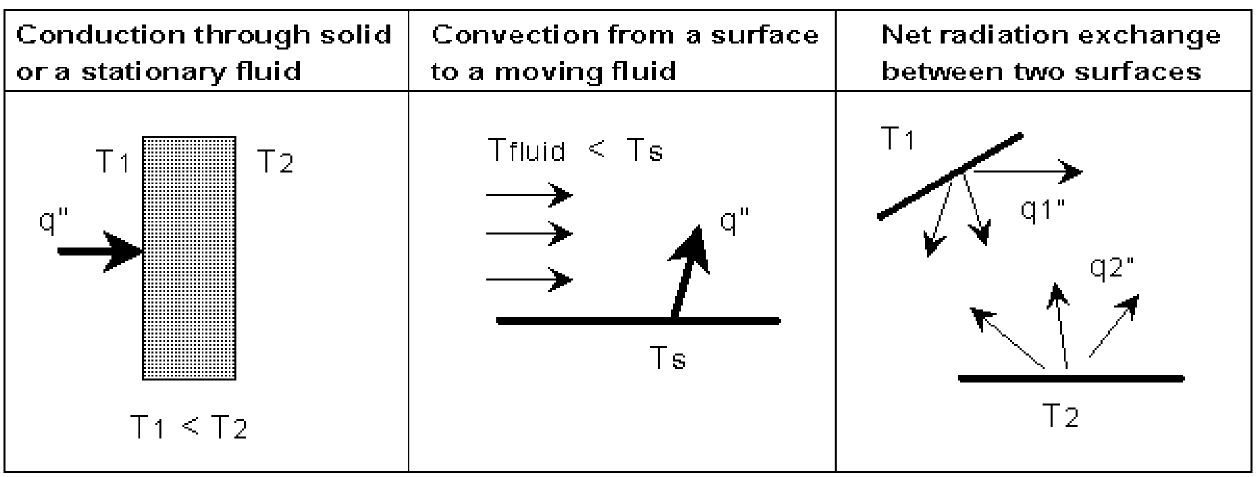


Figure 9: Heat Transfer Modes (Bergman, T. L. Introduction to Heat Transfer. Hoboken, NJ: John Wiley & Sons, 2011. Print.)

Conduction is the transfer of heat through a solid or a stationary fluid. q" is the symbol for heat flux and it is in units of watts/meter^2. Heat flux is the heat transfer rate in one direction per unit area perpendicular to the direction of transfer. The temperature gradient is $\frac{dT}{dx}$. K is a property of the material heat transfer occurs through and it is known as thermal conductivity. The equation for heat flux is $q" = \frac{k\ dT}{dx}$. In the figure below assuming that T1 is greater than T2, the equation for heat flux through the solid would be $q" = \frac{-k*(T_2 - T_1)}{L}$, where L is the thickness of the wall. See Figure 9 for locations of the temperatures and direction of the heat flux.

Convection is the transfer of heat through the movement fluids. In figure 10, convection is occurring when the campfire heats the air above the fire. The heat flux for convection is defined as $q" = h * (T_s - T_\infty)$. h is the convection heat transfer coefficient which depends on conditions in the boundary layer, which are influenced by surface geometry, the nature of the fluid motion, and other fluid thermodynamic and transport properties. T_s is the surface temperature, and T_∞ is the temperature of the fluid in the surroundings.

Radiation is the transfer of energy emitted by matter that is at a nonzero temperature. Emission may occur from all solids, liquids, and gasses. The equation for radiation is $q" = \frac{q}{A} = \varepsilon\sigma(T_s^4 - T_{surroundings}^4)$. This expression provides the difference between thermal energy that is released due to radiation emission and that is gained due to radiation absorption. This heat transfer mode is seen in figure 10 as the electromagnetic waves from the campfire warm the person's hands.

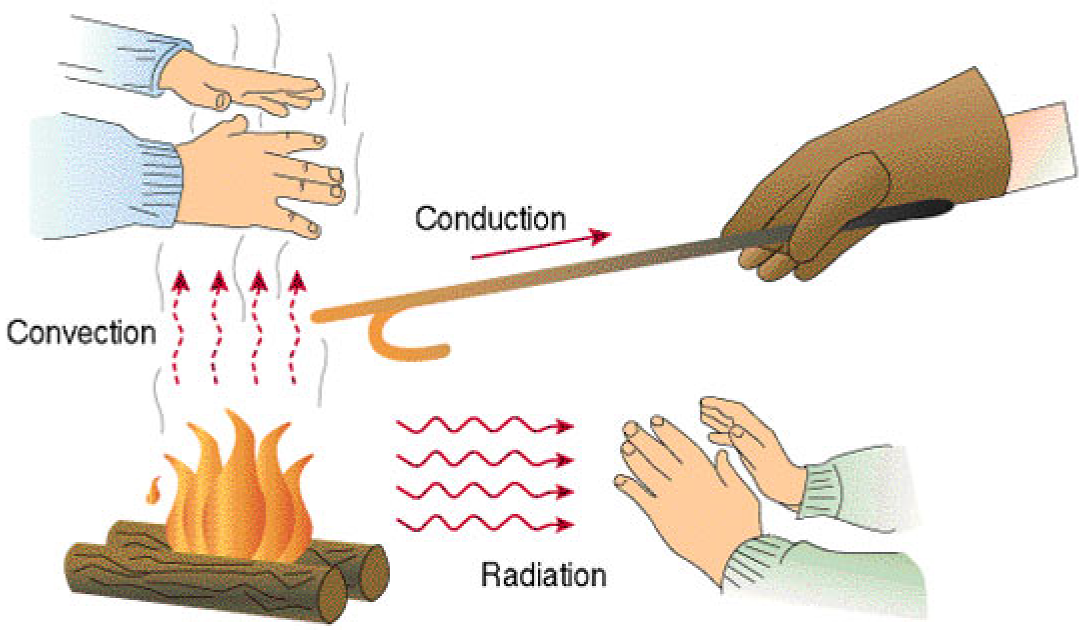


Figure 10: Heat Transfer illustration with a campfire as a source of heat ("Thermal Energy Transfer: Conduction, Convection, Radiation."Schoolworkhelper. N.p., n.d. Web. 04 Dec. 2014.)

2.5.2 Circle Packing

In considering space-saving techniques, there would ideally be the highest possible density of vial to container space. A scientific technique called circle packing was used to determine the most efficient way to pack uniform circles into other shapes. Figure 13 illustrates the most efficient packing of circular vials into a container space for five or ten vials in particular (Freidman).

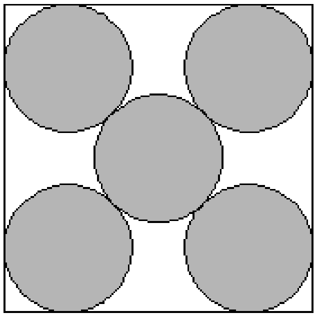


Figure 11: $s = 2 + 2\sqrt{2} = 4.828+$

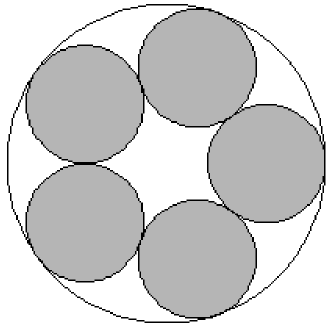


Figure 12: $r = 2.701+$

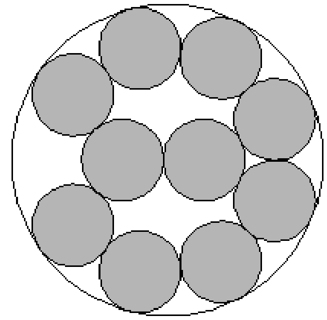


Figure 13: $r = 3.813+$

Optimal Circle Packing for Various Shapes and Circles (Freidman)

2.5.3 Temperature Monitors

There are two temperature monitors that are used at CSM to ensure quality and temperature compliance during shipment. There must be a consideration into the temperature reading technology as well account for space during design of the packaging product.

Figure 14: TempTale Temperature Monitor

Figure 15: El Pro Temperature Monitor

The TempTale and ElPro both use similar technology. The TempTale product design uses a self-calibrating circuit. This means that every time a monitor is started, the microprocessor determines the circuit resistance by using a high precision resistor in place of the thermistor. This allows the unit to compensate for any effects the electronic circuit has on accurate temperature readings over the life of the product. A properly assembled unit will hold an accuracy of between +/- 0.5° C and +/- 1° C depending on the temperature range in which it is used. Therefore, a TempTale monitor does not need to be "recalibrated" over its useful life.

These monitors work by translating the change in resistance due to temperature into temperature. A negative temperature coefficient (NTC) occurs when a physical property (such as thermal conductivity or electrical resistivity) of a material lowers with increasing temperature, typically in a defined temperature range. For the materials inside these two monitors, electrical resistivity will increase with increasing temperature.

2.6 Applicable Standards

2.6.1 FDA Requirements and Other Shipping Guidelines

There is a growing list of documents, legislation, requirements, recommendations and guidelines on the current regulatory environment of cold chain management:

- The EU Guide to Good Manufacturing Practice, Annex 13
- The Guidelines on Good Distribution Practice (GDP) of Medicinal Products
- CDC Guidelines for Maintaining and Managing the Vaccine Cold Chain
- WHO Guidelines on the international packaging and shipping of vaccines
- PDA Technical Report 39
- The US Code of Federal Regulations
- US and European Pharmacopoeia

The Federal Food, Drug, and Cosmetic Act (Act) prohibits the interstate shipment (which includes importation and exportation) of unapproved new drugs. Thus, the importation of new drugs that lack FDA approval, whether for personal use or otherwise, violates the Act.

Three key regulations from the FDA that address cold chain are:

21 CFR 203.32 "Prescription Drug Marketing – Drug sample storage and handling requirements."
This subpart (D--Samples) contains two parts that stipulate that (a) "Storage and handling conditions" not adversely affect the drug and (b) manufacturers, distributors of record, and their representatives comply with all compendial and labeling requirements.13
21 CFR 203.36 "Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party recordkeeping" looks at "comarketing agreements" with any third party involved in shipping and storing drug samples. This section states that the manufacturer or distributor is responsible for record keeping and documentation and must comply with the Prescription Drug
21 CFR 211.150 of Subpart H: Holding and Distribution - "Distribution procedures" states that these products must be shipped within:
"…appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs."
(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all stored drugs.

(f) Recordkeeping" states that drug distributors must maintain records and inventories that show receipt and distribution or "other disposition" of prescription drugs. These records must include the source of the drugs, the address of the location that the drugs were shipped from, the identity and quantity, and the dates of receipt/distribution/other disposition. Records must be kept and accessible for inspection for 3 years after the date of their creation.

The first clause of 21 CFR 203.32 states that authorized distributors must store drugs in conditions that will maintain their integrity and effectiveness. The second clause states that the labeling of the drugs must comply with compendial and labeling requirements.

21 CFR 203.36 states that the shipping service must keep records and documentation.

21 CFR 211.150 states that the shipping service must keep records of source of the drug, address to and from shipping, as well as dates for three years after the drugs have been created.

2.6.2 Testing Methods

Testing methods will follow the International Safe Transit Association (ISTA) 7 Series "Temperature Test for Transport Packaging." It is a development test to evaluate the effects of external temperature exposures of individual packaged products.

The cyclic test profile we are utilizing is a 72 hour international expedited airfreight transport for the winter and summer profile. For the winter profile, the lowest temperature will be -10°C, and for the summer profile, the max temperature will be 35°C. These cyclic test profiles cannot be displayed in this report due to copyright issues.

Chapter 3 DESIGN DEVELOPMENT

3.1 Method of Approach

The team is using a five phase design processes to solve the identified need. Please reference Figure 16 for graphical summary.

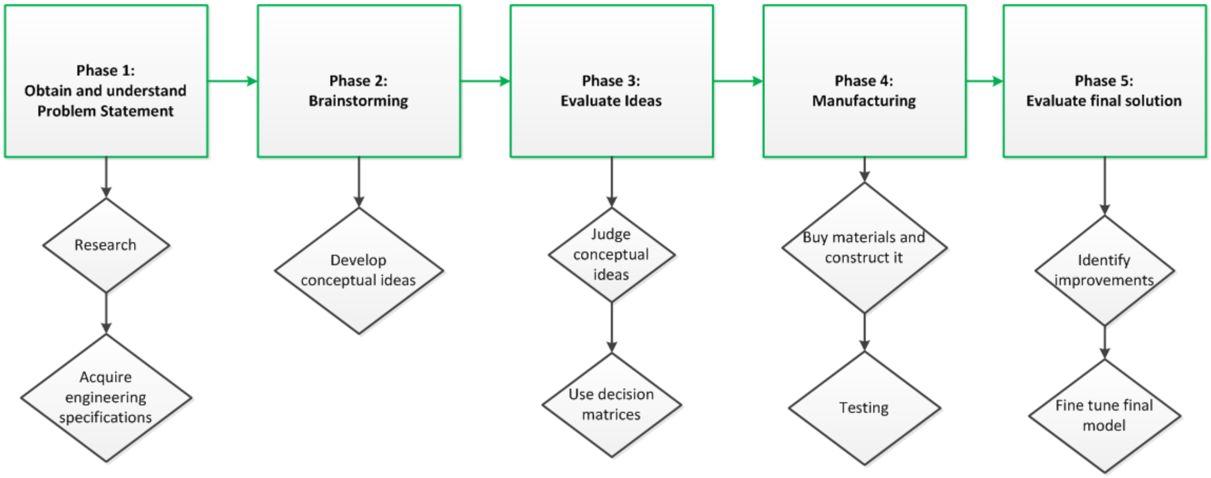


Figure 16: Basic Design Process

Phase 1 includes specification, development, and planning. In this phase, extensive background research is required to fully understand the problem. From this, customer requirements were identified which led to a list of engineering specifications, as specified in the Objectives section. The team identified materials, protocols and resources required for additional research testing.

Phase 2 is Conceptual Design. Concepts were produced by idea generation techniques such as brainstorming. Many potential solutions were explored and modeled to create basic proofs of concept. Using decision-making tools such as a design matrix, conceptual ideas were weighted to identify five top contending solutions. These potential solutions will be discussed with the sponsor in a design review to ensure that all the customer requirements are satisfied. Phase Two is an iterative process with expected failures and re-designing. During this phase, the team will also complete base line testing of commercial products. That is, the team will verify R-values of at least three different commercial products such as the Credo Cube using the Cal Poly Packaging Department testing equipment and protocol. This information will be used to compare data generated from modifications to the commercial products as well as novel prototypes.

In Phase 3, Product Design, the final solution will be evaluated with the sponsor and a report will be generated. During this stage, numerical analysis will be complete and a physical working prototype will be manufactured as the Minimum Viable Product (MVP).

Phase 4 is testing. Analysis, inspection, and testing will qualify product to engineering specifications. In cases of failure, a decision will be made to reiterate Phase 2 or move to Phase 5.

The final stage, Phase 5, will involve improving the MVP and fine-tuning it to fully meet the specifications. In cases of failure, the team will identify potential solutions but may not be able to implement them. At the Design Expo, a final report will be presented to the sponsor, faculty advisor and College of Engineering.

3.2 Concept Generation

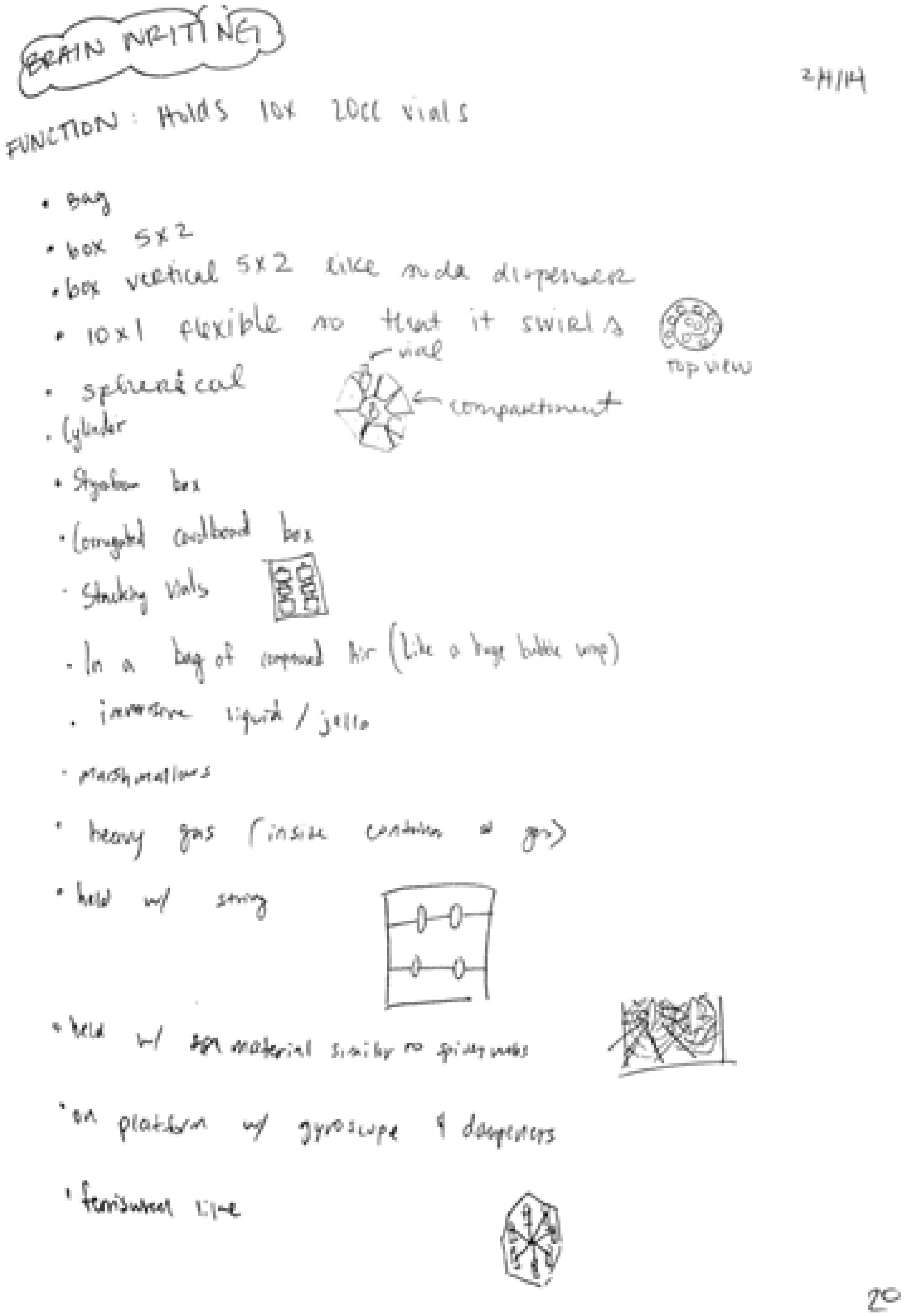
3.2.1 Ideation

Extensive background research on current temperature control packaging methods, methods of insulation and related applications was conducted as recorded in BACKGROUND. During research ideas were generated by first defining product functions.

Functions identified were:

- Holds 10x20mL vials in the smallest space possible
- Maintains 2-8C for 96 hours
- Holds standard (TempTale, ElPro) temperature monitor
- Protect Vials from breaking

From those functions, idea generation tools such as Brainwriting, Brainstorming and SCAMPER were utilized to generate concepts specifically addressing one function. Brainstorming is a technique of gathering a list of ideas spontaneously contributed by a group. No concept judgment is allowed during brainstorming, encouraging the most creative ideas. The idea of brainstorming is that it is fast-paced and ideas are either new or built on previous ideas. Brainwriting is similar to brainstorming, however, ideas are recorded on a single piece of paper instead of a board visible to all members. One group member writes down as many ideas as possible to fit the specific function in an allotted amount of time. The paper is then passed to the next group member to build on. Please reference Figures 17 and 18 for examples of ideation techniques.



BRAIN WRITING

2/4/14

FUNCTION: Holds 10x 20cc vials

- Bag
- box 5x2
- box vertical 5x2 like soda dispenser
- 10x1 flexible so that it swirls (top view)
- sphereical (vial, compartment)
- Cylinder
- Styrofoam box
- Corrugated cardboard box
- Stacking vials
- In a bag of compressed Air (like a huge bubble wrap)
- immersive liquid / jello
- marshmallows
- heavy gas (inside container w/ gas)
- held w/ string
- held w/ material similar to spider webs
- on platform w/ gyroscope & dampeners
- ferriswheel like

20

Figure 17: Brainwriting Ideation Technique

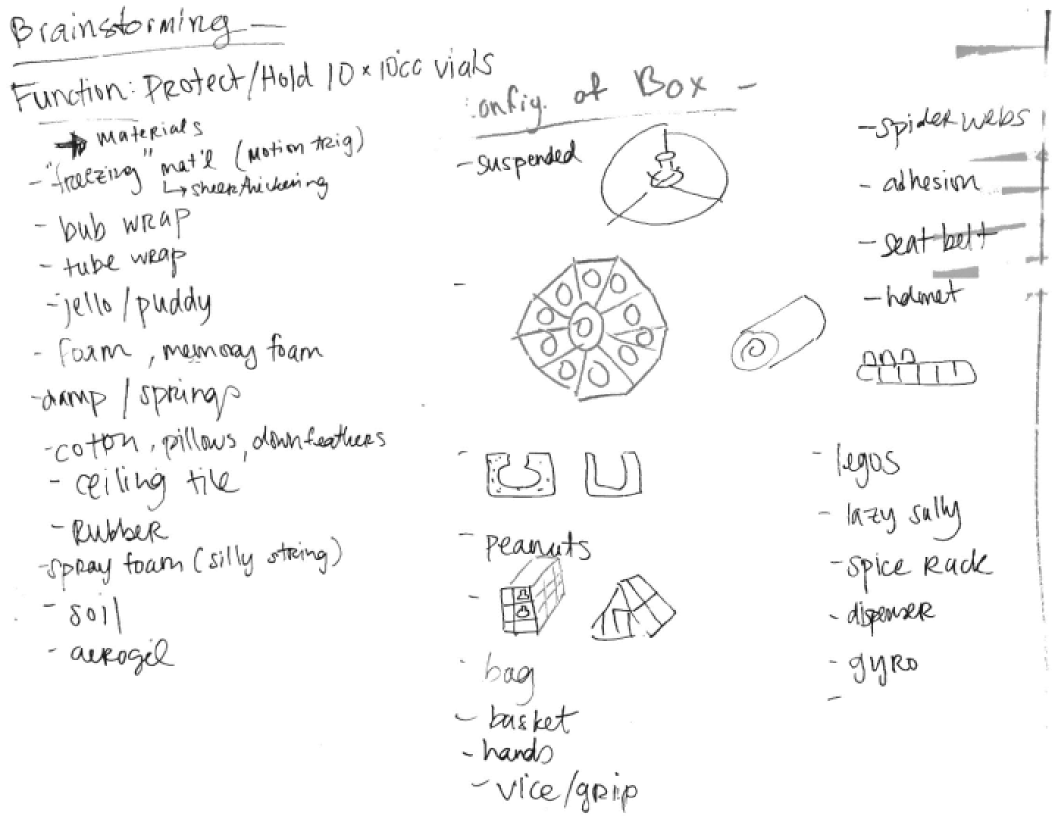


Figure 18: Brainstorming Ideation Technique

Attributes of the ideal product were also identified as:

- Reusable
- Durable
- Reliable

While attributes were not used for concept generation techniques, it was important to identify those features as driving design factors. From these techniques hundreds of concepts for each function were created. Several top concepts were modeled to have an idea for the feasibility of the concept. See Figures 19-24 for several concepts explored. In most cases shown, foam peanuts represent insulation and pink construction paper represents phase change material. The rolled up blue paper represents a vial.

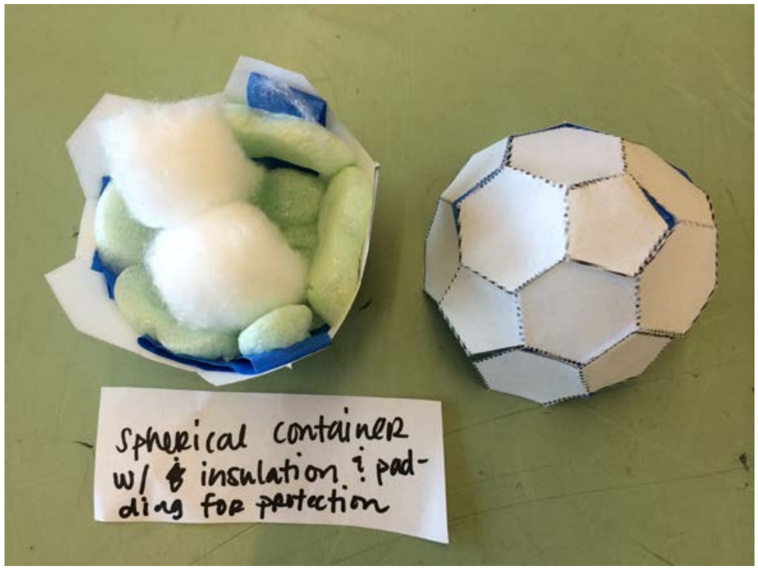


Figure 19: Spherical Container Concept with lease surface area

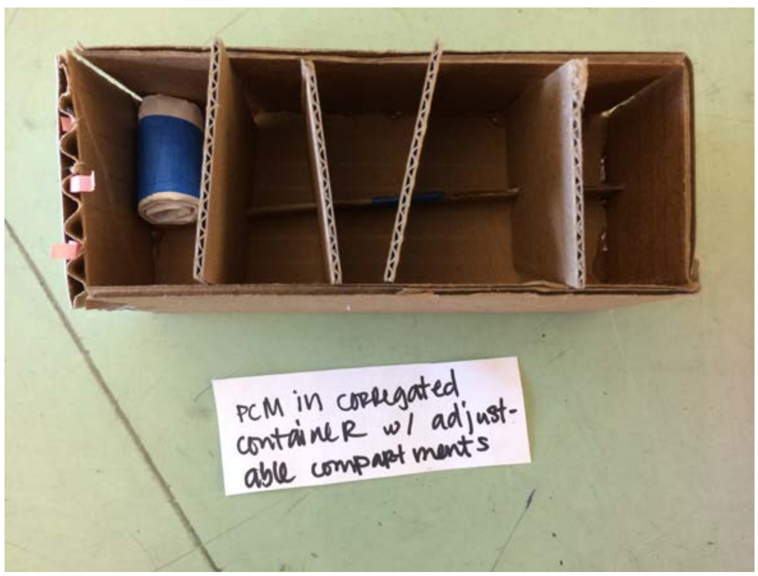


Figure 20: Versatile PCM-filled corrugated container concept

Figure 21: Rolled-up Logcake PCM Concept

Figure 22: Particulate PCM Concept

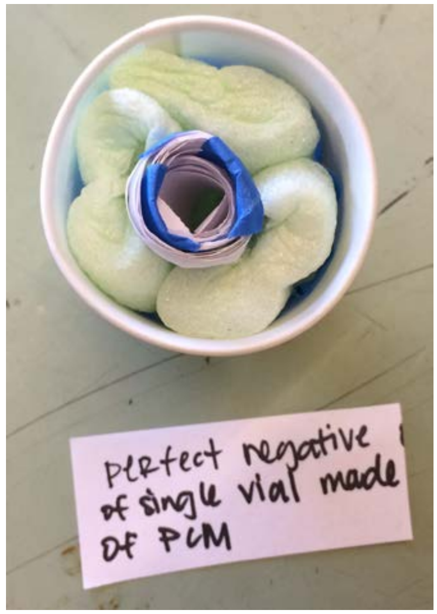


Figure 23: PCM For Individual Vials Concept

Figure 24: Refrigerator Concept

This technique was iterated for every design concept generation throughout the design process.

3.3 Top Concept Selection

In order to select one of the hundreds of ideas generated from the many brainstorming strategies, multiple types of matrices were implemented. Figure 25 shows the process of controlled convergence that will aid us in selecting the best solution.

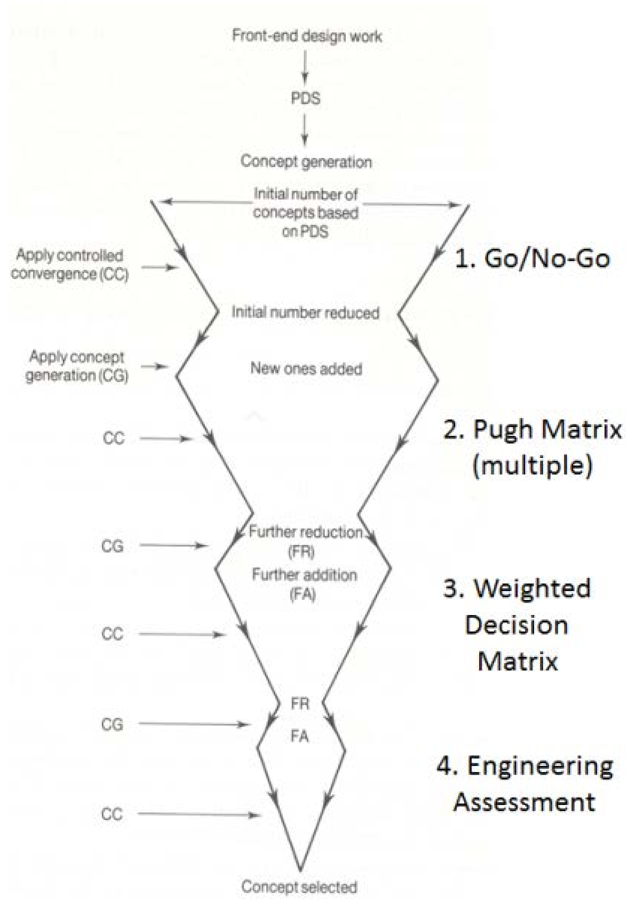


Figure 25: Controlled Convergence Diagram [Pugh]

When unable to come up with anymore ideas for each function, a quick go no-go elimination process was used. This go no-go process quickly dismisses unrealistic ideas to simplify the list of ideas.

After slimming down our list of ideas for each function, a Pugh matrix implemented for each function compared to the datum (Credo Cube). The Pugh matrix helps provide insight on which concept will be able to satisfy the customer requirements. All criterions are compared to the datum in order to identify if the new potential solution is better or worse. Although the concept that seems to be the best according to the Pugh matrix may not actually be the best since some of the criteria carry more weight than others. Figure 25 is an example of a Pugh matrix that assisted in idea selection.

According to the controlled convergence diagram, the next step is to implement decision matrices. Decision matrices are very similar to Pugh matrices except, each criterion (customer requirement) is weighted. Weights for each criterion were established as a team according to discussions with CSM. Ratings for each customer requirements were ranked out of 10 and each rating is them multiplied by the weight percentage and summed for the grand total. Therefore the concept that seemed to be the best in the Pugh matrix may not be the best according to the decision matrix. Below is a design matrix used for a function of our project, see Table 8.

Table 8: Decision Matrix of Concepts

				Concept			
				Passive: Flexible PCM roll, sealed, tiered w/ insulation		Passive: Negative PCM rigid panels w/ insulation	
	Criteria	Weight (1-10)	Weight (%)	Rating	Weighted Score	Rating	Weighted Score
Reliability	Protect Vials	10	13	8	104	7	91
	Maintain 2-8C for 96hr	10	13	7	91	8	104
	Durable (low failure)	9	12	6	72	9	108
Cost	Manufacturing Cost	6	8	6	48	3	24
	Material Cost	6	8	7	56	4	32
Shipping Cost	Optimize dimensions	8	10	5	50	7	70
	Lower weight	7	9	7	63	7	63
Reusability	Reusable (100 x IF high cost)	5	6	7	42	8	48
Efficiency	Flexible	3	4	3	12	0	0
Compliant	Have space for temp monitor	3	4	6	24	6	24
Safety	Not hazardous	8	10	9	90	9	90
"Green"	Bio-degradable	2	3	5	15	5	15
	Total	**77**	**100**		**667**		**669**

Functions were combined in order to find the best solution. For instance, different ways to protect vials were combined with different types of insulation and method of cooling. Another factor in the final product will be the shape of the container. Cylinders provide the smallest amount of volume and surface area but cubes are easier to manufacture. The most important decision to make for the final product was to decide on an active or passive cooling method.

To optimize dimensions, analysis into the effect of geometry was done. The ideal container would have the smallest surface area for modes of heat transfer while having enough room for the 10 vial payload. The results of the analysis can be seen in Table 9 and calculations for the dimensions can be seen in Appendix E.

Table 9: Results of Shape Optimization Analysis

Shape	Diam (m)	Side A (m)	Side B (m)	Height (m)	Surface Area (m^2)	Volume (m^3)	V/A (m)
Cube		0.092	0.092	0.092	0.051	0.0008	0.0153
Rectangular prism		0.046	0.115	0.046	0.032	0.0002	0.0077
		0.055	0.055	0.092	0.027	0.0003	0.0107
Cylinder	0.0876			0.046	0.025	0.0003	0.0112
	0.0621			0.092	0.024	0.0003	0.0116
Sphere	0.1318				0.055	0.0012	0.0220
Hexagonal prism	0.092	0.069	0.0473	0.046	0.030	0.0007	0.0231

While a cylinder shaped container would have the least heat transfer, it is more difficult to manufacture and handle. In a weighted decision matrix between the two, there was no significant difference. Since the surface areas of a cylinder and a rectangular prism with a square base had only about 10% difference, both container shapes were applied to top concepts.

Tables were created for the negatives of the vials and thickness of insulation in order to find an optimized balance between VIP thickness and amount of PCM. Since minimizing volume was one of the biggest priorities, we can increase the VIP thickness in hopes to reduce the amount of PCM substantially. Or vice versa, decrease VIP thickness and increase amount of PCM, thus creating this table will allow us to judge which will produce a smaller overall volume.

Increasing the thickness of VIP will yield a reduced heat load; therefore it will require less energy to maintain the temperature at 5C. Increasing VIP will only decrease the heat load to a certain extent. An interesting phenomenon that was realized while creating these tables is that VIP will begin to increase the heat load after two inch thick. This is due to the increase in surface area; the larger the outer surface area, the more area to transfer heat due to radiation, see Appendix E.

Additional research and calculations were also done for this concept with an alternative insulator. Aerogel has a thermal conductivity about 5 times more than that of VIP, Therefore with the same packaging as VIP, it required 5 times the amount of PCM in order to counter the heat load the package was seeing. After these findings (see Appendix E) , the idea of using aerogel as an insulator was thrown out.

The tables started with the smallest possible internal volume and the dimensions were increased little by little until the right combination was identified. This allowed us to calculate the maximum amount of PCM to fit inside the container, but if the amount of PCM can't counter the heat load, the container must increase in size.

3.3.1 Top Conceptual Designs

3.3.1.1 Concept 1

Concept 1 is based on utilization of all space as a cooling method. The design consists of two tiers of PCM containers that are perfect negatives of the vial payload acting as the secondary container. The two PCM "negatives" are then surrounded by insulation. The reusable system is then placed into a single use tertiary standard corrugated shipping box.

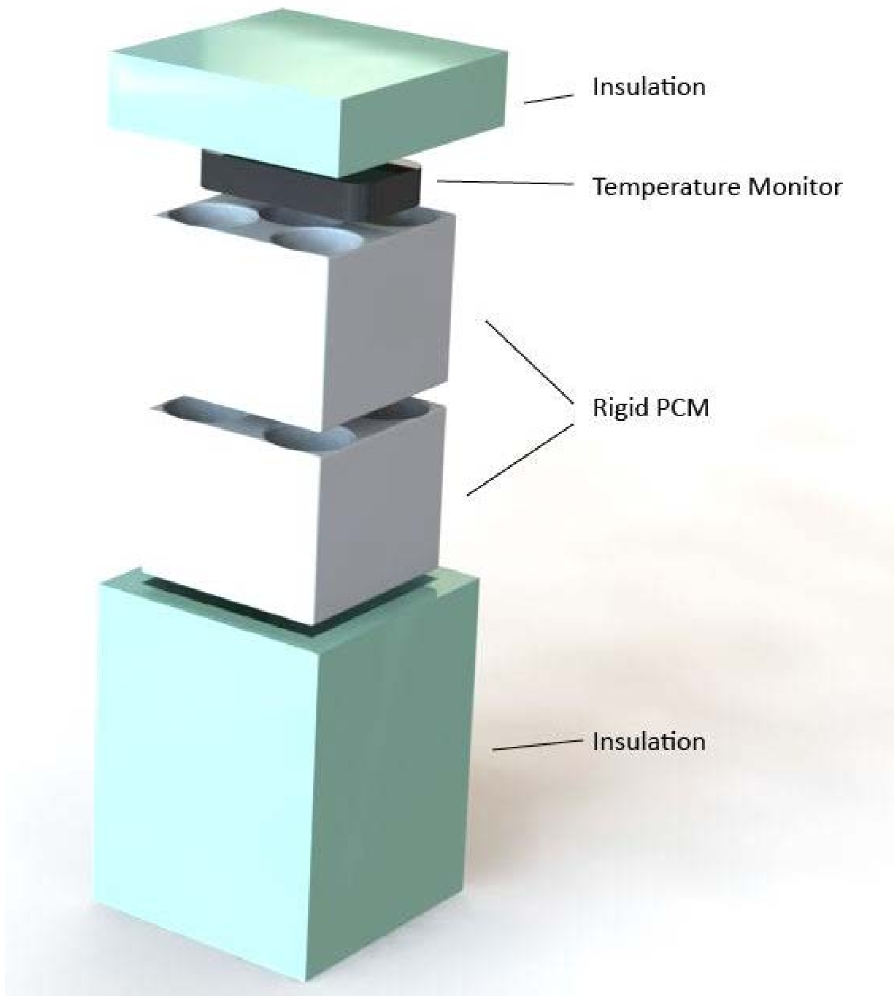


Figure 26: Concept 1 Exploded View

When looking the heat transfer for this design, the assumption is made that there is no convection due to air between the phase change material and the vials. There is only conduction occurring between the phase change material and the vials.

$$Q = kA\frac{\Delta T}{L}$$

Q represents the energy that is absorbed by the Phase change material, k is the value of insulation, L is the thickness of the material, and ΔT is the temperature range from 25 to 5 C.

In comparison with a Credo Cube, energy is required to keep the air between the phase change material and the insulation at 5 C.

$$Q = mc\Delta T$$

Q is the energy required to keep the air surrounding the phase change material at 5 C. m is the amount of air in the package, c is the specific heat capacity of air and ΔT is the temperature range from 25 to 5 C where the air temperature is at initially to where it needs to be at 5 C.
Q for the credo cube is

$$kA\frac{\Delta T}{L} + mc\Delta T$$

Unless the air between the insulation and the phase change material is less than 5C, a phase change material with a negative of the vials need to absorb less energy to maintain 5C.

Figure 27: Concept 1 Top View

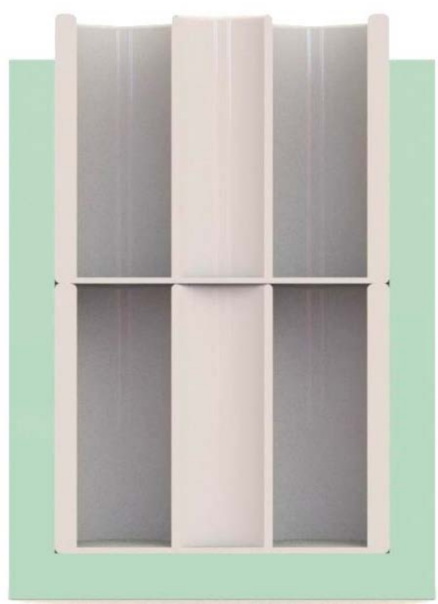


Figure 28: Concept 1 Cross Section

From these assumptions, it was determined that Concept 1 will reduce PCM compared with the Credo Cube by approximately 0.49kg.

Advantages
The design is the least complex and therefore most feasible between all concepts. The negative slots of vials would uniformly distribute the PCM around a payload and have very efficient head transfer between the PCM and product because of the lack of heat transfer by convection. The small surface area to large volume of PCM would have a fairly long phase change time. Additionally, the rigid container would be highly robust and is projected to have a long shelf life.

Disadvantages
The manufacturing of the container is extremely customized. It is projected to have a very high manufacturing cost. The design also does not allow for any flexibility in payload.

Cost
Cost estimates are based on preliminary analysis of worst-case scenarios. They are extremely rough and will be updated as detailed analysis is complete.

Table 10: Costs of Concept 1

QTY	DESCRIPTION	UNIT PRICE	TOTAL
2	Insulation	20	$40.00
2	Phase Change Material	70	$140.00
1	Plastic Container for PCM	100	$100.00
	SUBTOTAL		$280.00
	SALES TAX		$21.00
	SHIPPING & HANDLING		$20.00
	OTHER		---
	TOTAL		$321.00

The thermoelectric system combination required an Excel spreadsheet in order to identify the optimized sized battery for the thermoelectric system and amount of PCM. To obtain some assistance in picking out a thermoelectric system, the website www.tetech.com allows you to input dimensions and a heat load, and then it provides a list of recommended thermoelectric systems. The optimization table measured out weight since the weight of the battery usually correlates to the dimensions. The numbers in the table are all in kilograms and the boxes highlighted in green are the optimized weights that will satisfy all engineering requirements.

After creating this spreadsheet and visually seeing what type of thermoelectric system we will need, this idea was dismissed. The dimensions of this thermoelectric system that would satisfy our requirements would be too bulky. Including the battery would make our container as big as the Credo Cube, if not bigger. From the spreadsheet created to find the optimized combination, it shows that 100% PCM will be the lightest option. Tables were created for a few different types of thermoelectric systems combined with PCM and the optimal solution was constantly 100% PCM. The lightest option means the smallest volume, since a battery, a heat sink, and PCM are involved, the volume increases drastically versus just PCM.

Figure 29: Thermoelectric Module

3.3.1.2 Concept 2

Concept 2 is centered on the idea of flexible phase change material. The idea is most similar to bubble wrap--except instead of air, the pockets are filled with PCM.

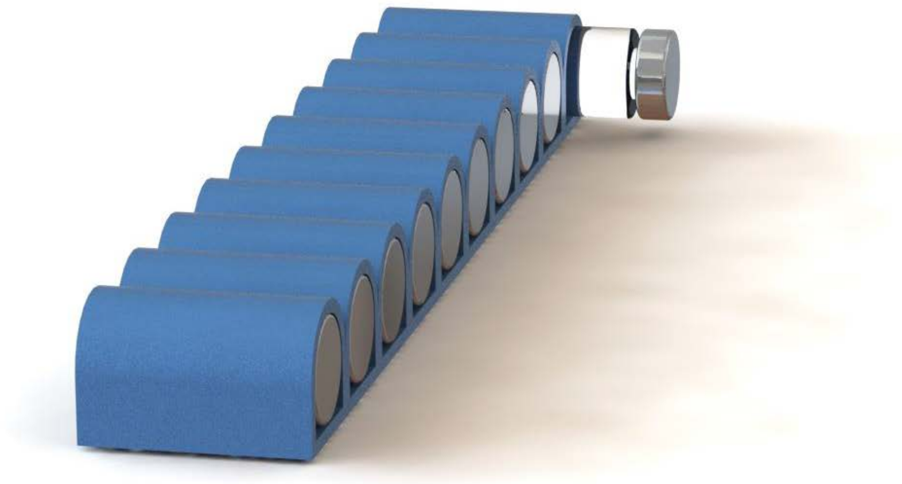


Figure 30: Concept 3

In analysis for this concept, air is again assumed to be negligible and that there would be no convection between the vial and PCM. Therefore, the same amount of PCM is needed as Concept 2.

Advantages

Traditional rigid containment of PCM reduces efficiency due to the thickness and weight of the container, the difficulty surrounding the payload, and the complexity of completely filling the container with PCM. Whereas flexible PCM would have the ability to uniformly distribute the PCM around a payload while being just as reusable. There is also a reduction in manufacturing costs when using thin films instead of heavy plastic. It is much more easily customized in dimensionally and would also allow flexibility in payload. In any configuration, the payload container would be filled with almost no air which would allow for more efficient heat transfer between the PCM and product. Flexible PCM also allows for circular configuration of the vials which is the most space efficient way to store the vials.

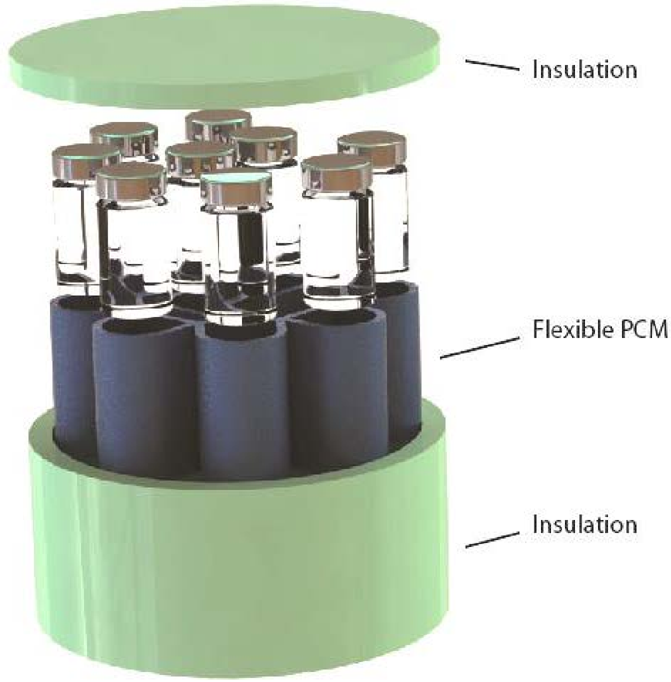


Figure 31: Exploded View of Concept 3

Disadvantages

Flexible PCM would have more surface area and less volume and would melt faster than a configuration with small surface area and high volume. No exclusive relation between volume of PCM and surface area exists. Consequently this concept will require extensive testing to verify preliminary calculations.

Cost

Cost estimates are based on preliminary analysis of worst-case scenarios. They are extremely rough and will be updated as detailed analysis is complete.

Table 11: Cost of Concept 2

QTY	DESCRIPTION	UNIT PRICE	TOTAL
2	Insulation	20	$40.00
2	Phase Change Material	70	$140.00
1	Plastic Flexible Container for PCM	50	$50.00
		SUBTOTAL	$230.00
		SALES TAX	$17.25
		SHIPPING & HANDLING	$20.00
		OTHER	---
		TOTAL	$267.25

3.3.1.3 Concept 3

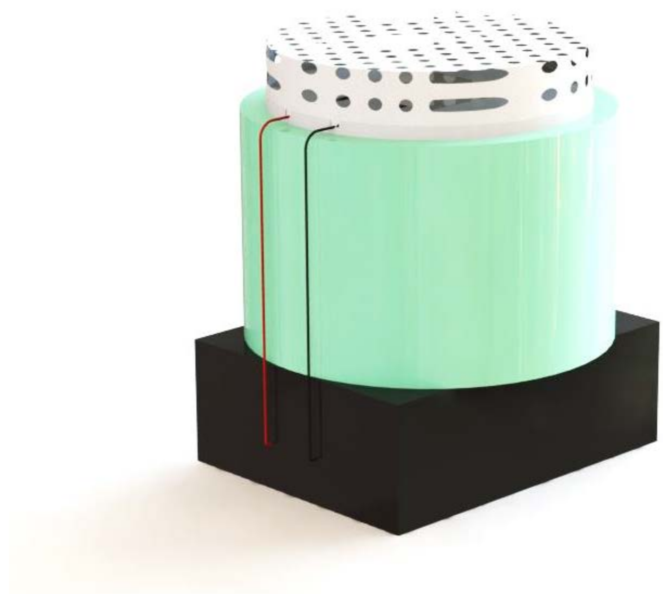


Figure 32: Concept 3 Model

Concept 3 is a combination of an active thermoelectric and passive PCM control system. The cold side of the thermoelectric system will be placed inside the payload area. Meanwhile the hot side will have a heat sink attached to dissipate heat (Rouse).

In thermal analysis of all designs, it was assumed that the insulator was vacuum insulated. As a result, only radiation was a mode of heat transfer into the container.

It was also assumed that the thermoelectric system is a small 5in x 10in x 10in container. The lid will house the thermoelectric plate in a slot. The governing equation for radiation is:

$$q_{radiation} = \frac{\sigma(T_1^4 - T_2^4)}{R_{total}}$$

Resulting in a thermal load of

$$\boldsymbol{q_{radiation} = 3.15\ Watts}$$

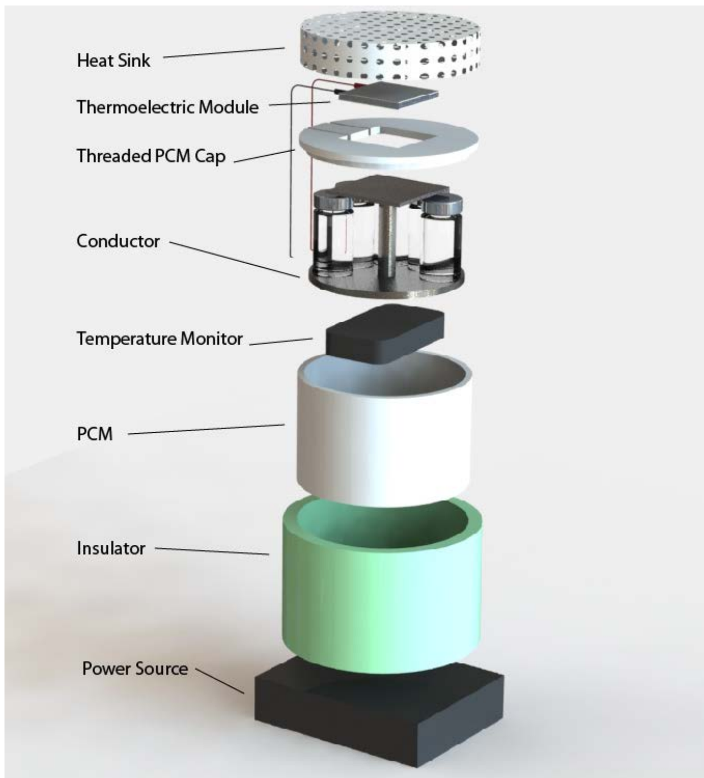


Figure 33: Concept 3 Exploded Model

Where T1 is the ambient temperature of 25C , T2 is the container temperature of 5C, and R_total is the total thermal resistance of the system. Please see Appendix C for complete calculations. Assuming a coefficient of performance of .4, the resulting power consumption is 7.88Watts at a maximum.

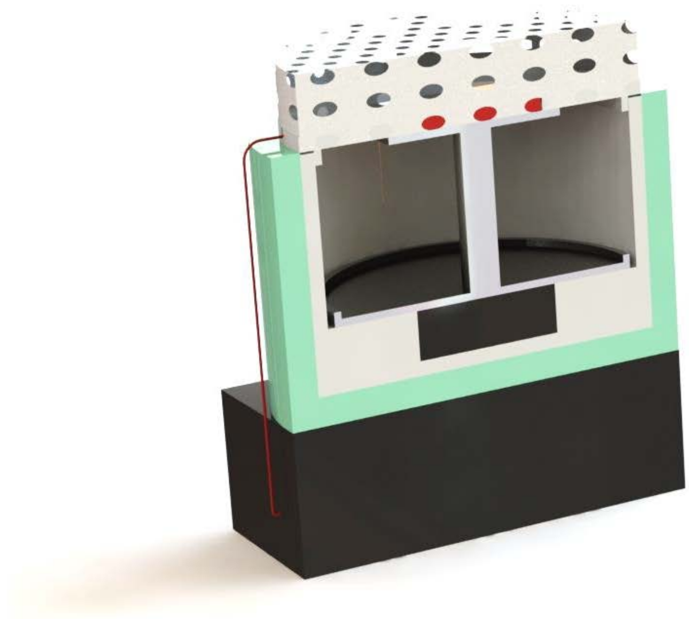


Figure 34: Concept 1 Cross Section

<u>Advantages</u>
Less PCM would be needed in any configuration (see Concepts 2 and 3) which would reduce weight, dimensions, and cost. The active system would only activate when it senses that the temperature of the container is deviating from the specified temperature. With further analysis, an optimization can be reached between the passive and active ratios. It is projected to be the most reliable concept out of the three presented. It is able to maintain 5°C for 96 hours with sufficient insulation and will have the proper cushioned secondary container to avoid damage to the vials.

<u>Disadvantages</u>
After calculating the estimated amount of heat that can enter through the insulated container, the size of thermoelectric system and battery was determined, see appendix for calculations. When assuming worst case thermal loading, there is a risk that thermoelectric system will need a fairly large or heavy battery (see appendix for potential components). Additionally, the hot side (negative) of the thermoelectric plate will give off heat. Being that the heat from the thermoelectric system and the battery will be enclosed in a cardboard box in contact with the vacuum insulated panels, it may require more power than anticipated in the calculations. This concept has the highest risk of feasibility and requires additional extensive calculations.

<u>Cost</u>
Cost estimates are based on preliminary analysis of worst-case scenarios. They are extremely rough and will be updated as detailed analysis is complete.

Table 12: Cost Estimation for Concept 3

QTY	DESCRIPTION	UNIT PRICE	TOTAL
1	Heat Sink http://www.mcmaster.com/#8822t13/=qxfhfd	10.48	$10.48
1	Thermoelectric Module http://www.tetech.com/Peltier-Thermoelectric-Cooler-Modules/Standard/TE-71-1.0-2.5.html	21.30	$21.30
1	Insulating Cap	10.00	$10.00
1	Conducting Cooler http://www.mcmaster.com/#89675k12/=qxfu9t http://www.mcmaster.com/#8965k85/=qxeox3	31.09	$31.09
1	Insulating Container	10.00	$10.00
1	Secondary Insulator	10.00	$10.00
1	Power Source http://www.amazon.com/Amstron-65Ah-Sealed-Battery-Terminal/dp/B002L9IHNA	175.00	$175.00
	SUBTOTAL		$267.87
	SALES TAX		$22.10
	SHIPPING & HANDLING		$60.03
	OTHER		---
	TOTAL		$350.00

3.4 Summary of Concepts

For the Thermoelectric / PCM combination, an optimization table was created. Vacuum insulated paneling from Nanopore will be used as the insulating material. The optimization table indicated that the ideal option is 100% PCM. Therefore having a thermoelectric system will not satisfy all customer requirements. The calculations below show the head load according to the dimensions of this concept. The thermoelectric system will maintain 2-8°C for over 96 hours, but it is not the best solution to this problem. Therefore, the concept of using a combination of a thermoelectric system with PCM was dismissed.

The next concept was having negatives of the vials which would be filled with PCM. This concept would have the smallest relative volume and weight. Since it had the smallest surface area and volume, less heat is able to enter the package. When less heat enters the package, less PCM is required to maintain the package between 2-8°C for 96 hours. These calculations below are for VIP at one inch thick for the sample calculations. The VIP can be thickened which would decrease the overall volume.

The last concept was the flexible PCM packaging. For this concept, the PCM will be held in a plastic packaging similar to how Otter Pops are sealed. After calculating the volume of the packaging for this container, the heat load and amount of PCM were obtained. For this concept, 2.02kg of PCM is required to counter the heat load for this size of package. Since a lot more PCM is required than anticipated, the flexible sleeves will be substantially bigger than how it was previously modeled in the product design review. Therefore there will be excessive gaps inside the packaging due to the large flexible sleeves.

Chapter 4 DESCRIPTION OF FINAL DESIGN

4.1 Overall Description

There are three basic functions of the package: protection and placement of the payload, creating a chilled temperature, and maintaining that temperature for the duration of a shipment. This is accomplished using a custom fixture, Puretemp Type 4 organic phase change material, and R34 vacuum insulated paneling. Ten vials are attached to a circular fixture which evenly spaces the vials within the package. To accomplish the 5-8C temperature range, the fixture is then placed into a bag filled with macro-encapsulated PCM beads. The bag is placed inside a rectangular box constructed of VIP. The thin bag enables the user to easily access the vials with minimal PCM loss. The final design is shown in Figure 35.

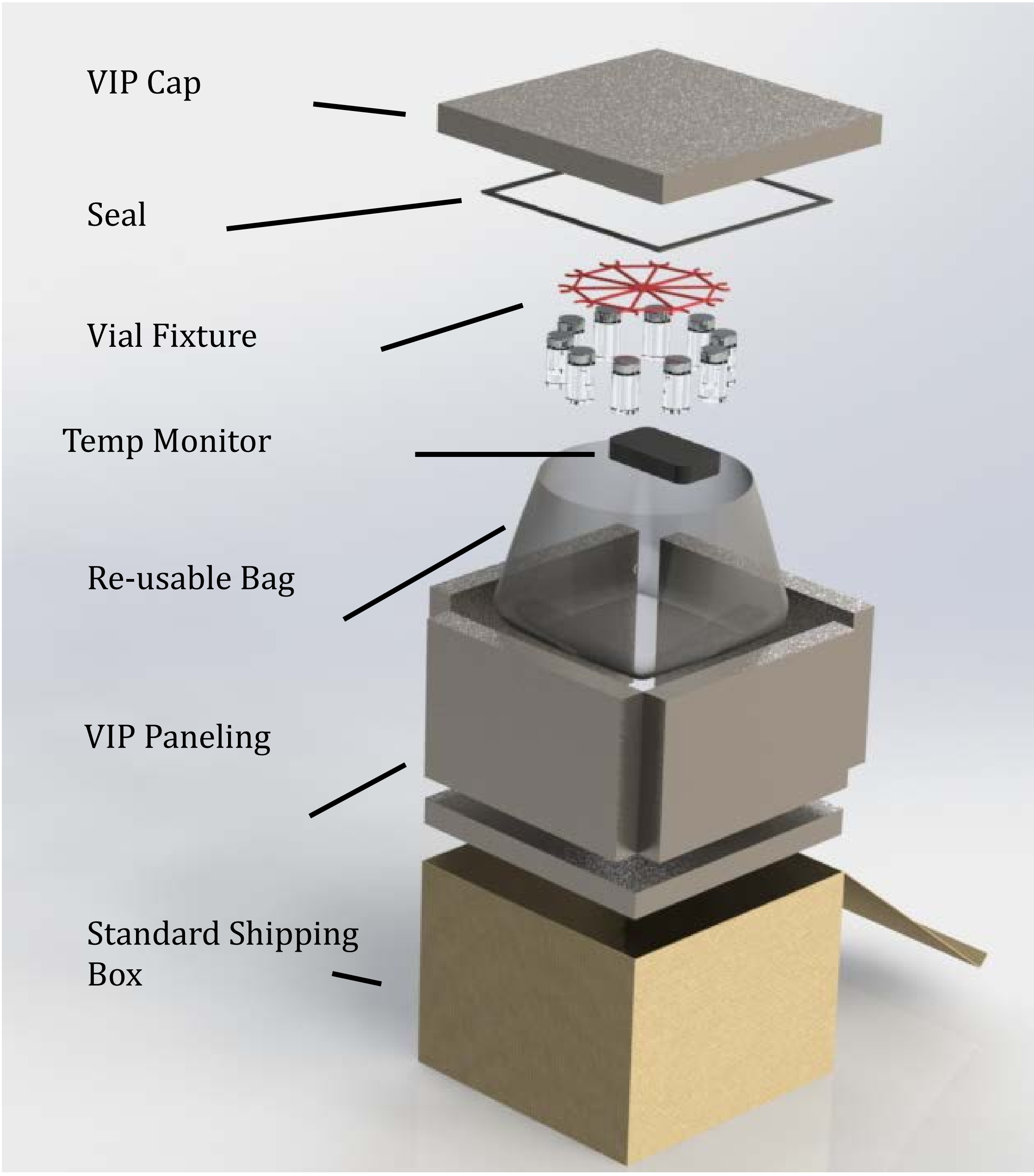


Figure 35: Exploded View of Final Design

4.2 Design Description, Material Selection, and Supporting Analysis

4.2.1 Macro-encapsulated PCM

4.2.1.1 Selection

Phase change material was selected as the component to maintain the payload at 2-8 °C. A high latent heat capacity was also desirable. Table 13 lists the available PCM vendors and specifications.

Table 13: Phase Change Material Vendor Specifications

Name	Phase Change Temperature (°C)	Density (kg/m^3)	Latent Heat Capacity (J/g)	Cost (Min $) or ($/lb)
Phase Change Material Products Limited				
A8	8	773	150	$422.25
A6	6	770	150	$422.25
A4	4	766	200	$422.25
A3	3	765	200	$422.25
A2	2	765	200	$422.25
RGEES, LLC				
PCM-OM05P	5	880	198	$150
PCM OM06P	5.5	780	260	$150
Microtek Laboratories, Inc.				
MPCM 6	6	x	162	$4/lb
MPCM 6D	6	x	162	$4/lb
ENTROPY SOLUTIONS INC.				
PureTemp 4	5	880	195	$5/lb
PureTemp 6	6	860	170	$5/lb

PureTemp 4, from Entropy Solutions Inc. was chosen as the material due to its relatively low cost and high latent heat capacity. The PCM organic-oil based which is appealing as the product will be "green" and non-toxic. As an additional prototyping appeal, unlike Rgees, LLC and Phase Change Material Products Limited, there is no minimum purchase required from Entropy Solutions.

The containment phase change material was then chosen to be "macro-encapsulation." Macro-encapsulation from the chosen vendor consists of 20mm diameter polymer spheres filled with PCM. Figure 36 displays a to-scale representation of a couple of macro-encapsulated PCM spheres next to the payload.

Figure 36: To Scale Macro-Encapsulation Beads and 10mL vial

This design combines the advantageous features of previous concepts because it is readily available, durable, versatile and space-efficient. Since it was identified that manufacturing/encapsulation of PCM was difficult for production, purchasing the PCM already encapsulated via a readily-available vendor would be the most economical choice. While the vendor will not disclose the specific type of polymer, some assumptions can be made regarding the elasticity and rigidity of the macro-encapsulated spheres. The encapsulation would be more elastic than the "Negative PCM" concept which would reduce risks of putting the vials under compression. At the same time, the uniformity of the spheres will have more structural rigidity than the "Flexible PCM" concept and be less prone to puncture. The small size of the spheres still allow for high PCM to payload contact and utilizing all available space to keep the product chilled. However 20mm is not too small to be a contamination risk in any controlled environment. Most notably, a major advantage of the macro-encapsulation is that as the payload can be more variable as opposed to previous concept designs.

4.2.1.2 Analysis

Similar to the "Negative PCM" concept, the equation below using the vendor's published thermal values was used to determine the heat load. The load is dependent on several design choices including thickness of insulation, a design ambient temperature and the surface area of the package.

$$q_{load} = \frac{T_{ambient} - T_{inside}}{\frac{L}{k * A_s}} = \frac{T_{ambient} - T_{inside}}{R}$$

where

q_{load} = Amount of heat entering the system (package) through the VIP
$T_{ambient}$ = Outside surface temperature
T_{inside} = Inside air temperature
L = Thickness of insulation
k = Thermal Conductivity
A_s = Total external surface area
R = Thermal Resistance

Again, from the heat load, the amount of PCM required could be determined for varying lengths of time using:

$$m_{PCM} = \frac{q_{load} * \Delta t}{h_{lf}}$$

Since the PCM can no longer be assumed to fill the entire volume available, geometric considerations were made to account for air and polymer. According to Sphere Packing science, the efficiency (or density) of randomly packed spheres in a rectangular container is about 0.64. Sample calculations of maximum amount of PCM in a specified geometry can be seen in Appendix E.

By fixing internal dimensions and varying insulation thickness, a parametric study was made to minimize the external dimensions while also ensuring the PCM required was met. Table 14 below displays the required PCM for a package with internal dimensions 8in x 8inx 6in. These dimensions limit the amount of PCM possible to 2.92kg at a maximum. Only insulation thickness at least 1in thick would reduce the head load enough so that the required amount of PCM would be less than the maximum available.

As a result, the heat load and corresponding PCM amount was found to be

$$q_{load} = 1.58 \text{ Watts}$$

$$m_{PCM} = 2.88 \text{ kg}$$

Before obtaining this final result, several of these studies at varying internal dimensions were performed and iterated to optimize both size and weight.

Macro-encapsulated PCM has a space efficiency of 10-15% because part of the weight is due to the polymer shell. This was accounted for by using

$$m_{Bead\ PCM} = m_{PCM} * \text{Bead efficiency} + m_{PCM}$$

$$m_{Bead\ PCM} = 2.92\text{kg}$$

Therefore, the final amount of macro-encapsulated PCM needed to maintain the payload between 2-8°C for 96 hours is 2.88kg.

Additional examples of the parametric study as well as detailed analysis can be found in Appendix F.

4.2.1.3 Risks/Maintenance and Repair Considerations

While the team is confident in the above analysis, some assumptions and design decisions were made.

First, the published average thermal conduction (k) value for VIP was used instead of performing physical verification using the actual component to be incorporated into the product. However, this is considered to be a small risk as the vendor is fairly reputable.

An additional design decision was to choose an ambient temperature that drives the heat transfer. $T_{ambient}$ in the equation presented earlier is actually more accurately described as the surface temperature of the package. With the possibility of both ambient and surface temperature varying greatly during a shipment, worst case scenarios were considered. During the 96hour transit time, the worst case scenario would consist of the package being exposed to direct sunlight for all available hours of daylight during summer. As a team, this scenario was deemed unreasonable and uneconomical. To mitigate for this risk, the design surface temperature was chosen to be 35°C for the entire duration of 100hours. In the International Safe Transit Association test protocol for 72 hour international summer shipments, 35°C is the highest temperature tested and only in two cycles of 6 hours. Therefore, the design surface temperature assumption is very conservative, and the risk is reduced to very low.

Lastly, failure modes are considered. Since the phase change material will be macro-encapsulated in a plastic casing, there is a possibility of yield due to thermal expansion and contraction or stresses. However, the final design is able to contain up to 984 spheres, and failure of all spheres at once is highly unlikely. The phase change material and casing should be replaced with another PCM macro-encapsulation in order to compensate for the loss.

4.2.1.4 Safety Considerations

Safety Considerations of this component include choking hazards if ingested or slip hazards if stepped on.

4.2.2 Macro-Encapsulated PCM Containment

A plastic bag is used in order to prevent the loss of PCM when the recipient is procuring the payload. The height of the bag will be higher than the height of the box preventing the PCM from falling out of the bag.

A Velcro hook tab or loop tab will be placed on either side of the bad so that the bag can be closed securely. This will allow the recipient to open the bag simply and reduce the loss of PCM.

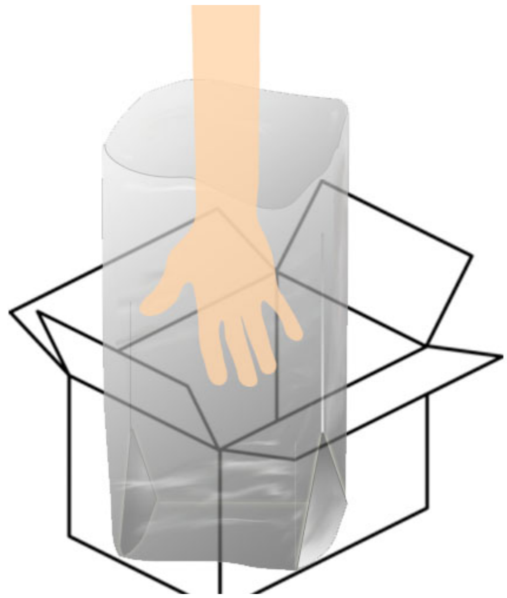


Figure 37: Illustration of hand in Bag in Box

A plastic bag was selected in order to have the lowest unit cost compared to other materials.

If the plastic bag holding the phase change material yields (develops a tear), the bag should be replaced with an untorn bag.
If the either hook or loop Velcro tabs has come off the bag, a new one should be adhered to the plastic bag.

To avoid danger of suffocation keep this plastic bag away from babies and children.

4.2.3 VIP Containment

4.2.3.1 Selection

Vacuum Insulated Paneling was selected because it has the highest thermal insulation values of any material.

Figure 38: Kevothermal VIP

Of all the VIP vendors only Kevothermal™ produces paneling less than 12x12 square feet. As a result, Kevothermal™ was selected as our vendor.

Table 14: List of Materials with the Highest Insulation Values

Material	m²·K/(W·in)	ft²·°F·h/(BTU·in)
Vacuum insulated panel	5.28–8.8	R-30–R-50
Silica aerogel	1.76	R-10
Polyurethane rigid panel	1.23–1.41	R-7–R-8
Polyurethane rigid panel aged 5–10 years	1.10	R-6.25
Polyurethane rigid panel initial	1.20	R-6.8
Polyurethane rigid panel aged 5–10 years	0.97	R-5.5

VIP is a thermal insulation enclosure which has been evacuated of air. If the membrane wall of the VIP has been punctured, the thermal insulation will not be as effective. Due to the unknown process the manufacturers undertake to produce this seal, VIP should be discarded if the vacuum inside of the enclosure has been compromised.

4.2.3.2 Risks/Maintenance and Repair Considerations

All of the risks in the assumptions are related to heat transfer calculation limitation. Javier De La Fuente, an assistant professor of Industrial and Packaging Technology, said that the majority of the heat transfer would occur at the edges of the package, where there are gaps between the insulation. Due to the team's limited knowledge of heat transfer, this heat transfer calculation was not able to be done. We plan to solve this issue by iterating our design according to empirical testing. Another risk from our assumptions is the one-directional heat transfer for the VIP. In our calculations, we assumed that heat transfer will only occur in one direction through the VIP, and not in the perpendicular direction. Again, the team plans to resolve this issue with iterating based on the testing.

The edges of VIP may be sharp and so care should be taken when working with them. Additionally, puncturing the VIP seal will degrade the insulating properties. Scratching, bending, denting or puncturing the VIPs should be avoided.

VIP has a lifetime of 3 years. This is due to the loss in vacuum in the seal, which will degrade the insulation properties. Currently Clinical Supplies Management resolves this issue by manually checking the VIPs to feel if the vacuum is holding. If the VIP seems soft, they are replaced with a new VIP.

A rubber bulb seal was added in order to seal the top VIP panel to the rest of the panels. This would theoretically reduce the amount of heat transfer between the edges of the sides of the box and the top panel. Different types of adhesives will be tested on the vacuum panels to select the optimum adhesive to attach the seal to the VIP.

Ethylene propylene diene monomer (EPDM) was selected as the material for the seal because of its common use. It is a good insulator with a thermal conductivity value of 0.2 W/m-K.

The seal may degrade over time and may have to be replaced.

4.2.3.3 Safety Considerations

The contents of the VIP are hazardous and should not be handled directly if the encasing were to accidentally torn or broken.

4.2.4 Vial Fixture

A plastic fixture was added to the project components as a method of keeping the vials from striking one another. Additionally, it will allow the vials to be spaced evenly among the phase change material, providing optimum heat transfer.

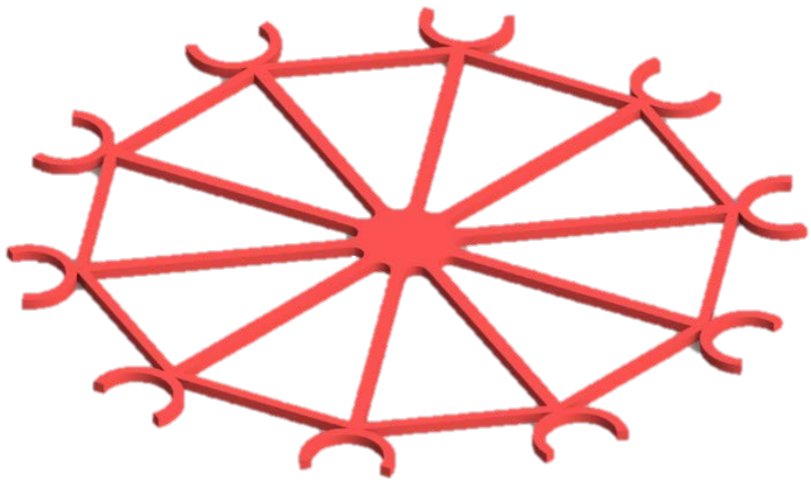


Figure 39: Vial Fixture Model

ABS Plastic was selected as the material for the plastic fixture because of its low cost and common availability as a filament in 3-D printing.

This component will be made of plastic and may yield at the arms due to repeated loading. If an arm has yielded, the arm should be re-adhered to the main structure or the entire structure must be replaced.

4.3 Cost Analysis

Because the VIP has a minimum purchase order of $1000.00 from the selected vendor, prototyping will consist of 10 units. The prototyping unit cost for one container was $129.31.

Table 15: Total Prototyping Budget

Unit Production Cost			
Material	**Unit Price**	**Quantity**	**Subtotal**
VIP	**$118.66**	**1**	**$118.66**
PCM	**$5.2/bag**	**1**	**$5.20**
Transient Packaging	**$3.31**	**1**	**$3.31**
Plastic Fixture	**$0.24**	**1**	**$0.24**
Seal	**$1.15**	**1**	**$1.15**
Tape	**$0.76**	**1**	**$0.76**
		Total	**$129.31**

In Table 17, the unit price of VIP is calculated from a bulk order of 4000 units. The unit price of the transient packaging is from a bulk order of 1000. The projected unit production cost is $70.92.

Table 16: Projected Bulk Production Cost for a Single Unit

Unit Production Cost			
Material	Unit Price	Quantity	Subtotal
VIP 1	$15.38	1	$15.38
VIP 2	$16.28	1	$16.28
PCM	$5.00/lb.	3.87 lbs.	$19.35
Transient Packaging	$0.37	1	$0.37
Plastic Fixture	$0.24	1	$0.24
Plastic bag for PCM	$0.00215	1	$0.00215
Seal	$0.94	4	$3.76
Velcro Tape: Hook	$0.012222	1	$0.012222
Velcro Tape: Loop	$0.012222	1	$0.012222
		Subtotal	$55.40
		Shipping	$11.08
		Tax	$4.43
		Total	**$70.92**

Chapter 5 PRODUCT REALIZATION

All of manufacturing of the components of the Mackage were done by outside vendors, except for the vial fixture which was 3-D printed by Yufay. The assembly of the Mackage was done by our team, MAC.

5.1 Manufacturing

The fixture was designed in SolidWorks, and printed with ABS plastic with a 3D printer. In order to obtain the correct fixture size the circumference of the vials were found, and designed in SolidWorks. The file was then exported as a STL file. The file was printed and the SolidWorks model was adjusted until the 3D model was able to hold the 10 mL vials.

Figure 40: 3D Printed Vial Fixture

5.2 Assembly

The vacuum insulated panels arrived with loose flaps of foil on the edges. These flaps were taped to the panel in order to prevent the flaps from tearing and allowing the VIP to lose the vacuum.

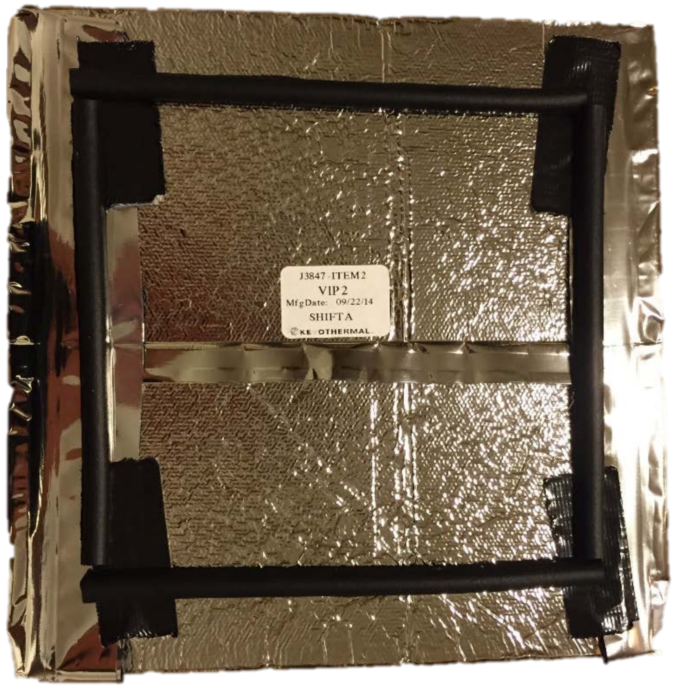


Figure 41: VIP with flaps taped and D shaped seal attached

Two methods were used in order to assemble the VIPs. The first method was placing the 9” x 9” panel flat on the bottom of the cardboard box. Four 8” x 5” panels were then placed, one at a time, on the inside sides of the cardboard box.

After the PCM, vials, vial fixture, and bag were placed inside, the 9” x 9” panel was placed above them and the package was closed and sealed.

The alternative method was cutting the D-shaped rubber seal into appropriate sized lengths and adhering them an inch away from the edge of the VIP. The VIPs were then assembled in the same way as the previous method.

Figure 42: VIPs in a cardboard box

Figure 43: Water Pearls

The polymer beads, also known as water pearls, were placed in a tub of water in order for the beads to absorb that water.

Figure 44: Hydrated Polymer Beads

Once the polymer beads were fully hydrated, they were placed in trays which were subsequently placed in the freezer. The beads freeze at 0°C.

Figure 45: Preconditioning Beads

Figure 46: Frozen PCM beads filled with H2O

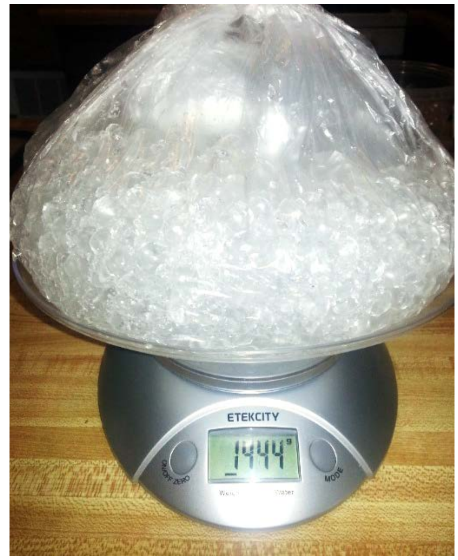


Figure 47: Weighed PCM

After the beads have frozen, they are taken out of the freezer and placed into a plastic bag. The bag is weighed and beads are removed or added to obtain the desired weight.

The plastic bag is then placed inside the cardboard box between the VIPs. The temperature monitor is turned on, and set to a delay start so that the monitor does not record the temperature when the package is not ready to be sent out. The temperature monitor is placed on top of the phase change material.

Figure 48: Beads, Payload, Fixture, and Temp Monitor

Figure 49: Bag folded over to prevent spillage

The bag is then folded over to a side of the package so that the interior components do not come out of the bag when the package is in transit. The top flaps of the cardboard box are then folded over and the flaps are taped to the box to ensure that they do not open in transit.

Figure 50: Ready to Ship Package

5.3 Notable Differences with Original Design

Polymer beads were used instead of the originally specified phase change material from PureTemp, PureTemp 4. This made several differences from the original design. With the polymer beads, the acting phase change material is water, which has different thermal properties than PureTemp 4.

The latent heat of fusion of water as well as the melting point, 334 kj/kg and 0 °C, were different than PureTemp4, with a latent heat capacity of 195 kj/kg and a melting temperature of 5°C. The melting temperature of 0°C was not in the desired specification of 2-8°C.

As a result, the scope of the project was changed from a product to replace to the Credo Cube to a prototype which would test the heat transfer tools that the team had created.

The heat transfer tool we used was a calculator which took in inputs such as the thermal property of the phase change material. Due to the fact that water has a higher latent heat, and the size of the polymer beads were larger than the PureTemp4, the dimensions of the box were adjusted. The size of the box designed for the PCM from PureTemp4 was 10" x 10" x 8", while the box for the water beads was 9" x 9" x 8". However, if we were able to obtain PureTemp4, we would use the original box size of 10" x 10" x 8".

Another difference with the water beads were that they were not reusable following a freeze-melt cycle. After a freeze-melt cycle the beads shattered with a small amount of compression. As a result, the reusability tests could not be conducted. Instead, the packages were used as a one use prototype to test the effectiveness of our PCM calculator.

5.4 Recommendations for Future Manufacturing

If this project were further pursued a few suggestions would be offered. First, 2 of the vacuum insulated panels lost their vacuum. Compared to the panels used in the credo cube, there is no hard plastic sealing around the VIPs. Upon inspection, the team came to the consensus that the current foil sealant for the VIP from Kevothermal is not adequate for preventing a leak. The team suggests that if any VIP is used, a hard plastic sealant is placed around it.

Another recommendation for future manufacturing would be to add the D shaped sealant to all of the VIP panels. We found that on average, the sealed VIPs were able to stay in the specified temperature range longer than the unsealed panels.

Chapter 6 DESIGN VERIFICATION PLAN

6.1 Specification Verification Checklist

Because the scope of the project changed, original engineering specifications have changed. There was no need for a reliability test since the prototyping PCM is intentionally single use and the melting temperature has been modified form 0 +/- 3 °C to 0 +/- 3 °C. For every specification, a corresponding test was conducted. Table 18 summarizes the specification and test description. See Appendix H for full Design Verification Plan Report. Sections 6.2-6.6 explain test results. See Appendix I for raw data and original vendor testing results.

Table 17: Design Verification Check List

Test #	Specification Reference	Test Description
1	Dimensions - 10 vials	Visual Inspection that vials fit inside package
2	Dimensions - Temperature Monitor	Visual Inspection that temperature monitor fits inside package
3	Handling/Usability	Credo Comparison using Timing Test for pack out
4	0 °C	Temperature Test for Transport Packaging (ISTA 7B)
5	96 hours	Monitor payload temperature for 100 hours under ambient conditions
6	Rigidity, 0 Vials cracked	Drop, Stress and Loading Test using FedEx standard
7	Real Environment	1 time air ship during weekend

6.2 Test 1: Visual Inspection of Vials

A visual inspection was performed to ensure that ten 10mL vials were able to be contained in a single new packaging product.

6.2.1 Test 1 Results

Test 1 Passed. Ten 10mL vials were successfully contained in the package.

Figure 51: 10 Vials in a prototype filled with required PCM

6.3 Test 2: Visual Inspection of Temperature Monitor

A visual inspection was performed to ensure that the TempTale or El Pro temperature monitor was able to be contained in a single new packaging product.

6.3.1 Test 2 Results

Test 2 Passed. The El Pro was successfully contained in the package, see Figure below.

Figure 52: Visual Test for Temperature Monitor Inside the MAC-kage

6.4 Test 3: Time Comparison with Credo Cube Pack-Out

One package was timed for assembly and disassembly to compare to Credo Cube handle-ability.

6.4.1 Test 3 Results

Test 3 Passed. Using the statistical program JMP, it was determined that the Mackage handle-ability is significantly less than the Credo Cube's. Dunnett's 0.05 means comparison was used.

Table 18: Handle-ability Timing Results

	Time to obtain payload (s)	
Trials	Mackage	Credo Cube
1	4	13.82
2	5.63	12.03
3	4.57	12.75
4	5.13	12.62
5	4.78	13.57
6	3.7	13.61
Avg.	4.635	13.07

6.5 Test 4: Temperature cycles per ISTA standard

Five samples with varying types of adhesive sealant on VIP paneling were cycled in one 96hr test. Because the team was concerned about possible leakage through the corners of the VIP, the corners of three samples where sealed using generic Duct Tape. At the request of the sponsor, two additional samples were not permanently sealed and left tightly packed in a standard corrugated shipping box. The Cal Poly Packaging Department's Thermotron temperature chamber was used to control ambient temperatures (as seen in Figure 53).

Figure 53: Packaging samples inside Thermotron test chamber

Due to ISTA copyright, the team is unable to publish the exact temperature cycling procedure. However, if the reader has access to the International Safe Transit Association "Temperature Test for Transport Packaging," please refer to Summer Profile for a 48 hour domestic transport cyclic test profile. This is also the same standard temperature cycling that the Credo Cube claims to last for 96 hours, as seen in Figure 54.

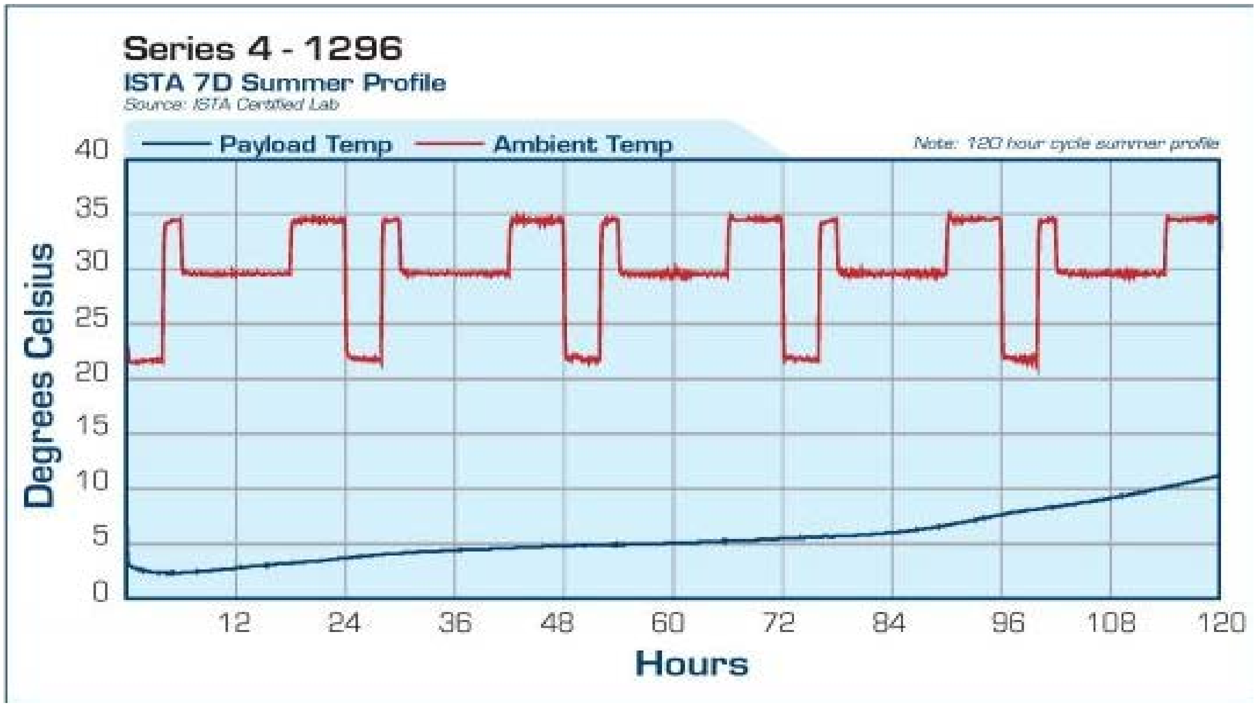


Figure 54: Credo Cube Temperature Loading ("Series 4 1296 [Credo Cube]", 2014)

Similar to this published data, the lowest ambient temperature tested in the Thermotron is -10°C and highest is 35°C. A single temperature monitor was placed inside the package to measure payload internal temperature and one outside in the temperature chamber to monitor package surface temperature.

6.5.1 Test 4 Results

Test 4 Failed. Out of all five samples, the shortest time before deviation was 48 hours and the longest time before deviation was 92 hours, as seen in Figure 55. After averaging temperatures of each lot, there was a temperature deviation from 0 +/- 3 °C at approximately 80 Hours for Lot 2 and 88 Hours for Lot 1, as seen in Figure 56.

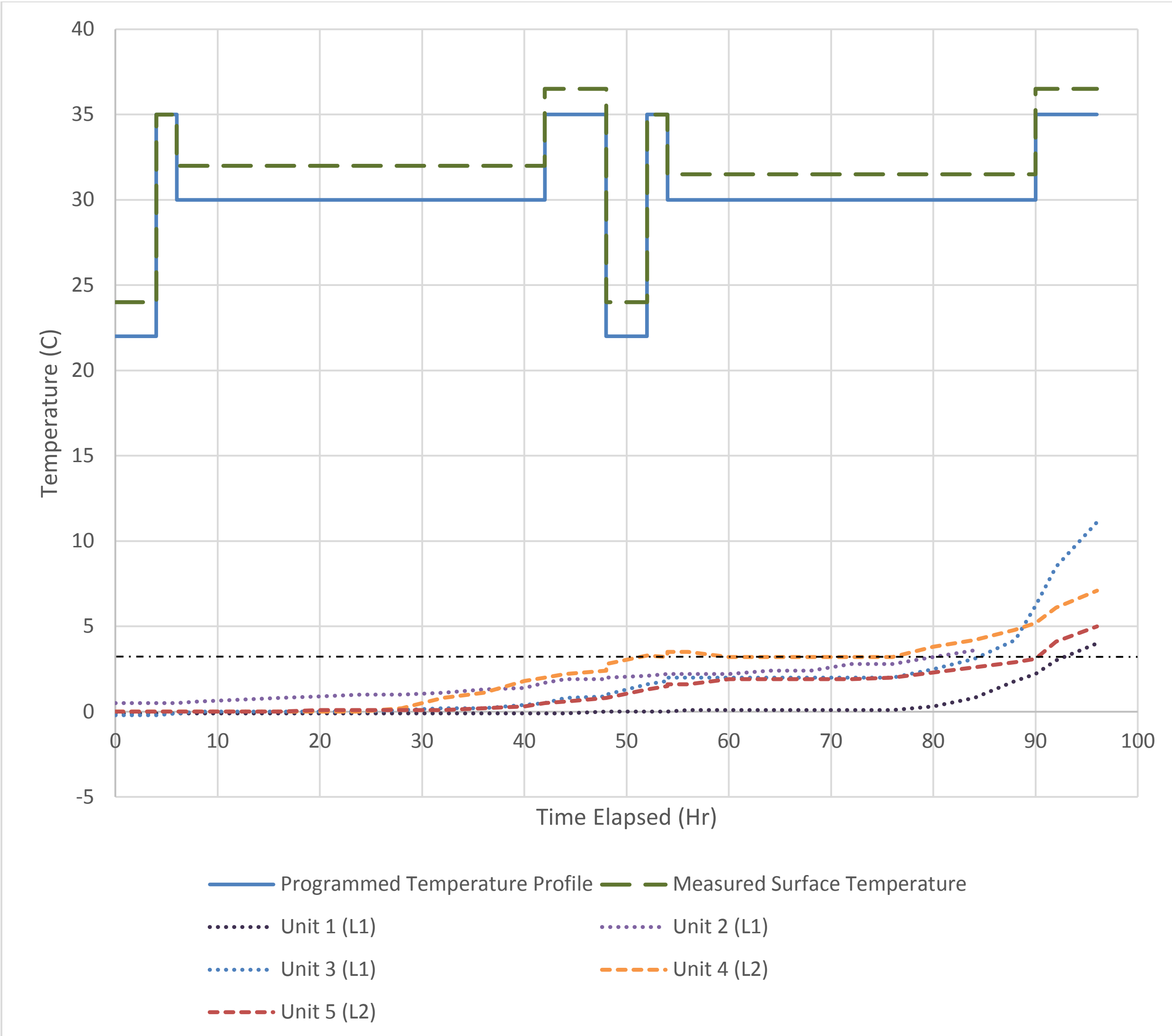


Figure 55: ISTA Temperature Cycling Raw Data

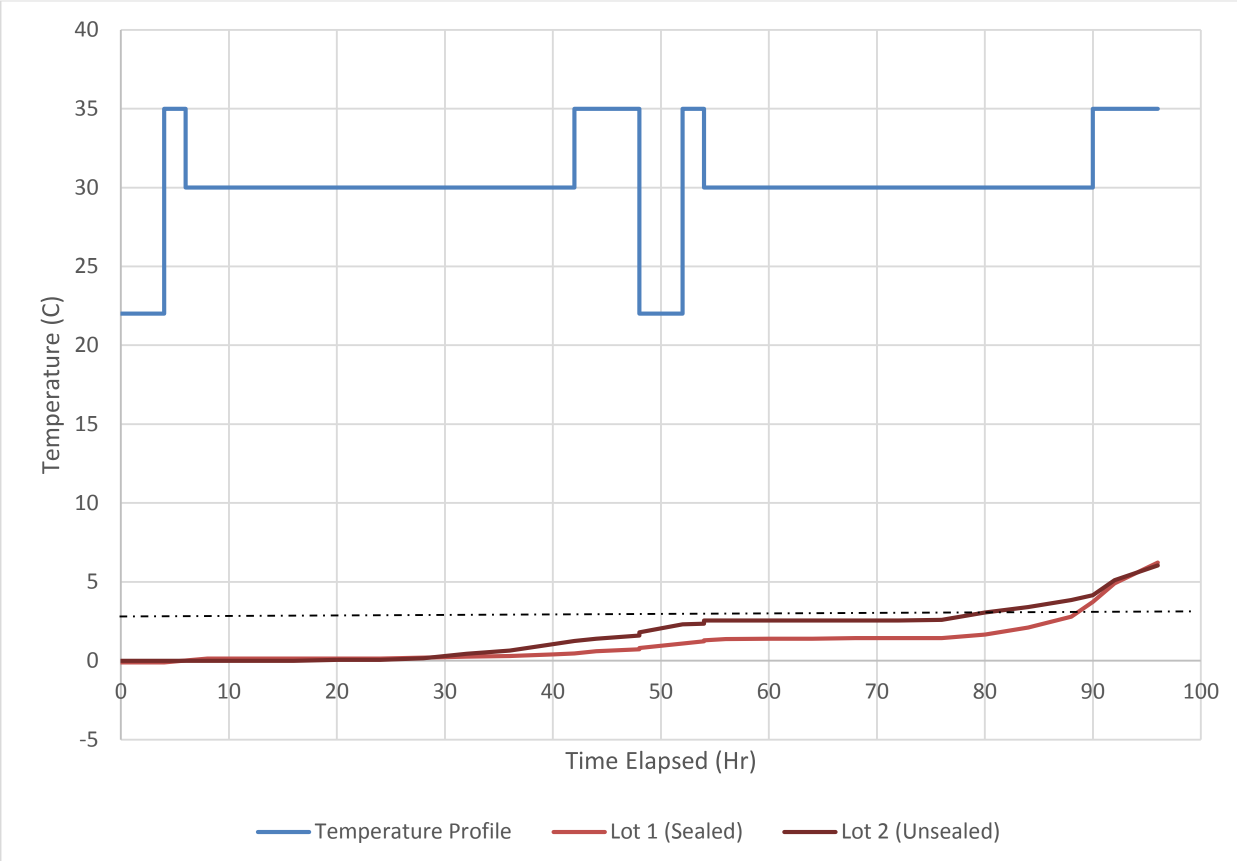


Figure 56: ISTA Temperature Cycling Averaged Data

6.6 Test 5: 100 Hour Test

The team created a 100 hour test because there are no standard procedures cyclic testing beyond 72 hours. A single temperature monitor will monitor the internal payload temperature for at least 100 hours. The sample will not be in direct sunlight and will be stationary throughout the test. Ambient conditions were recorded and overlaid with the internal temperature, as seen in Figure 57. One sample was tested.

6.6.1 Test 5 Results

Test 5 Passed. Deviation did not occur until 120 hours.

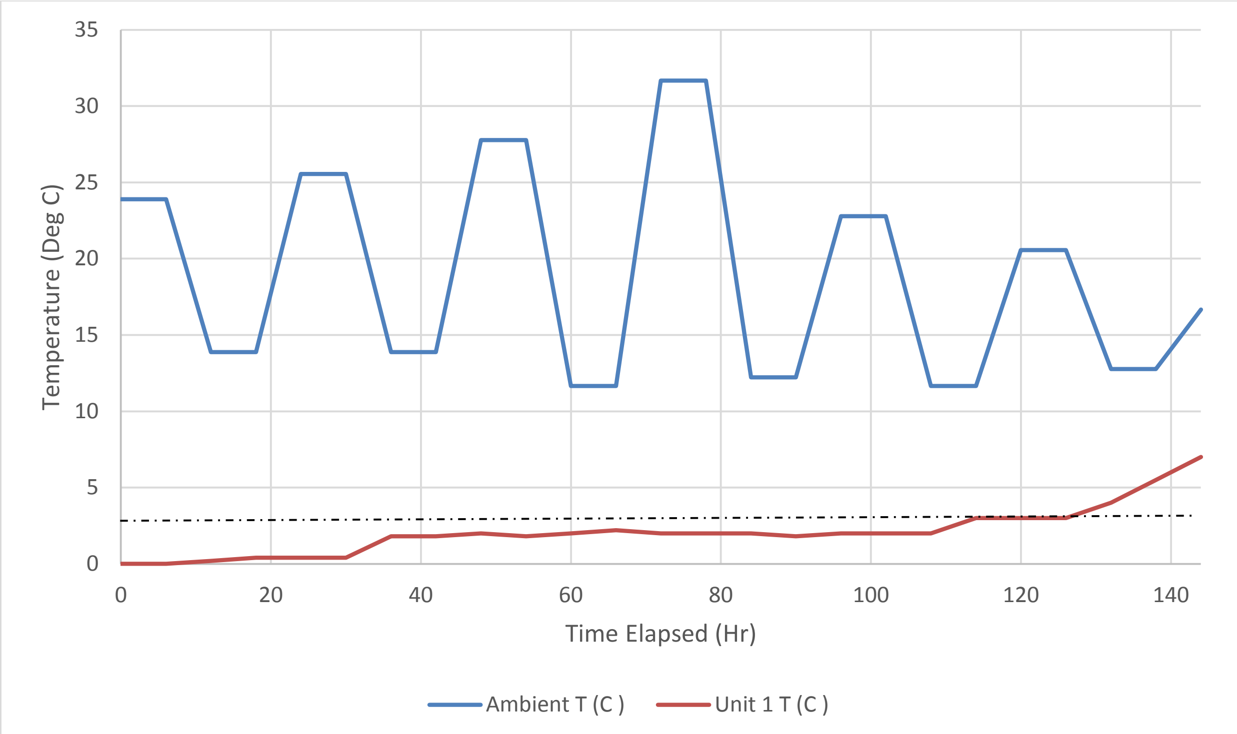


Figure 57: 100 Hour stationary temperature monitoring

6.7 Test 6: Drop Test, Stresses and Loading Tests

To simulate physical shipment conditions, the ISTA-6-FedEx-A protocol was used. The protocol was a series of three tests: Impact/drop testing from 30", compression testing with a load of 316lbf, and vibration testing for 60 minutes. These tests represent extreme conditions the packaging may encounter.

6.7.1 Test 6 Results

Test 6 Passed. Per FedEx standards, the samples failed the Drop and Vibration testing, as seen in Table 20. However, their failure criteria is different than that of the design team's. According to the report, "the test package failed due to the use of duct tape for tape sealing closure." The tape was re-adhered and the tests were completed. Per the MACkage team's specifications, there was no vial damage so the samples passed.

Table 19: Summary of FedEx Tests Results

FedEx Test			
Sample	Drop (30in)	Compression (316lbf)	Vibration (60 min Rotary)
1	Fail	Pass	Fail
2	Fail	Pass	Fail
3	Fail	Pass	Fail

6.8 Test 7: Real Environment Test

One packages was shipped via FedEx overnight shipment. This test is to ensure that temperature excursion, damage to vials, and structural failure do not occur during an actual shipment.

6.8.1 Test 7 Results

Test 7 Passed. As seen in Figure 58, there were no temperature deviations during the 18 hour period that the packaged was air shipped. Upon visual inspection, no vials were damaged and the package did not fail structurally.

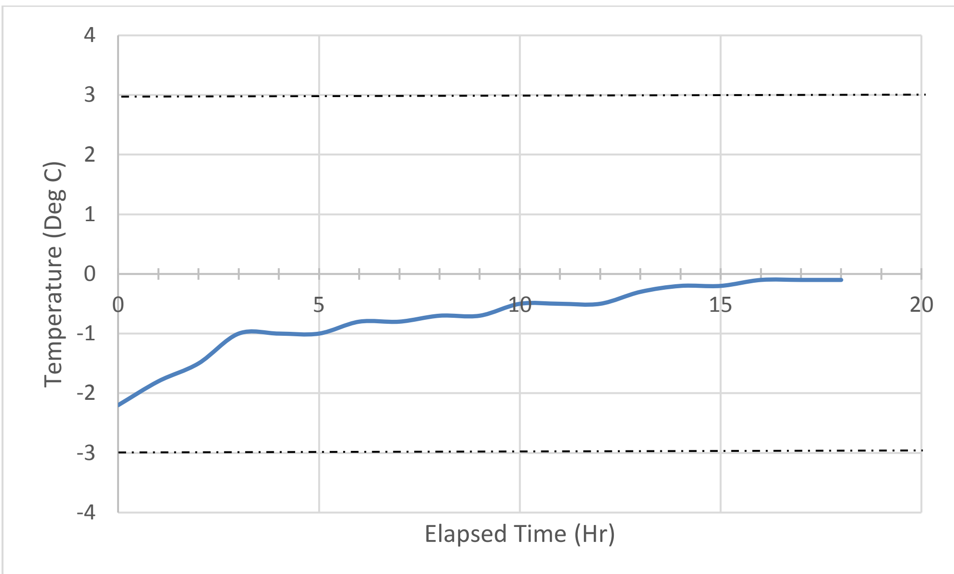


Figure 58: FedEx Overnight Shipment Internal Temperature Profile

Chapter 7 CONCLUSIONS AND RECCOMENDATIONS

Figure 59: Final Prototype

Ultimately, the goal of the team was to develop a final product that would be able to rival temperature controlled packages used in industry, particularly the Credo Cube. A summary of comparisons to the Credo cube can be found in Table 21. While the package was smaller, cost less and had a lower shipping rate, the chill time was 17% short of the 96 hour Credo Cube standard.

Table 20: Summary of Packaging Comparisons

	Credo Cube	Mackage	Reduction
Size (in.)	15 x 13 x 13.5	9 x 9 x 6	82%
Weight (lbs.)	21	6.6	69%
Unit Cost	$400	$129	68%
Unit Shipping Cost	$150	$43	71%

The team has some speculations explaining why the prototype did not reach 96 hours. First, there may have been greater leakage between VIP corners and through the long side of the VIP than anticipated. The high thermal resistivity of the VIP was only rated in the short direction and heat could have entered through the long side. This conclusion is backed by the fact that the unsealed packages deviated sooner than the sealed ones. Second, the number of samples was fairly small. A larger sample size may be a more accurate representation of variance, means and standard deviations of the prototypes. To mitigate this, the team recommends that future designs use protective casing and permanent sealing on all VIP paneling.

Additionally, because the prototype did not meet original specifications, the team developed a “PCM Tool” to assist the sponsor in any figure iterations of the design. The tool was programmed in Excel to be user-friendly. The tool can take inputs such as PCM and VIP thermal properties, PCM diameter, required internal temperature, and required external dimensions. Essentially, it is a parametric study that allows the sponsor to make informed future design decisions. Detailed tool instructions can be found in Appendix G. The team recommends that further testing be done if the sponsor would like to create a direct correlation between the outputs the PCM tool creates and the time, temperature, and size inputs. The easiest way to do this would be to apply a factor of safety to the “amount of PCM required” output. The factor of safety is also an input so that it can be empirically determined.

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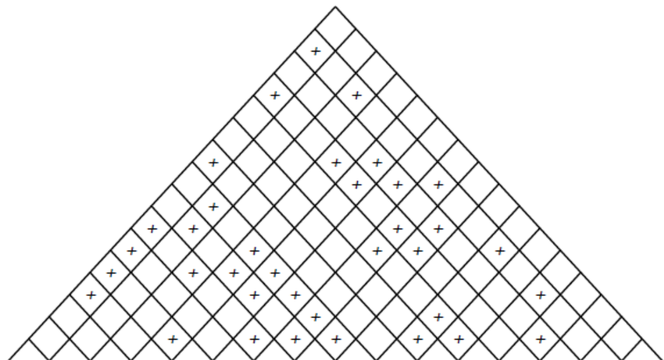
APPENDIX A: QFD, DECISION MATRICES

By first identifying customers, the team was about to utilize the House of Quality technique to derive engineering specifications. Customers of this product include CSM, Clinics/Hospitals, Patients, Operators, Shippers (FedEx, UPS, etc), and. Using Who, What, How, and How Much correlations and weighing them at the judgment of the team, metrics were defined to meet perceived requirements of all customers. Requirements that did not weigh well in the matrix were eliminated and requirements that weighed highly Requirements.

Correlations	
Positive	+
Negative	−
No Correlation	

Relationships	
Strong	●
Moderate	○
Weak	▽

Direction of Improvement	
Maximize	▲
Target	◇
Minimize	▼



WHO: Customers

Row #	Weight Chart	Relative Weight	CSM	Patients	Clinics/Hospitals	FDA	Fedex/UPS	Operator		Maximum Relationship	WHAT: Customer Requirements (explicit & implicit)
1		2%	5	1	0	0	0	0		9	10 Vials
2		9%	5	5	5	5	0	0		9	2-8 C
3		11%	5	5	5	5	2	0		9	Last for 72-96 hours
4		15%	5	5	5	5	3	5		9	prevent breakage of vials
5		4%	4	3	3	0	0	0		9	Reduced shipping cost
6		2%	4	1	1	0	0	0		9	Reusable
7		7%	4	4	4	3	0	1		9	Decrease handling time
8		15%	5	3	4	5	4	5		9	Safe
9		5%	2.5	1	2	0	3	0		9	Easy to store

Column #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Direction of Improvement	◇	▼	◇													
HOW: Engineering Specifications	Able to hold 10 vials	Maintain Temperature Tmax for 72 hours	Material Cost	0 Vials cracked after 10 foot drops (5) upon visual inspection	Maintains dimensions under tolerance under 100 lb axial load for 96 hours	In case vials break the container prevents the bio hazardous substance from interaction with human	Reduce the dimensions of the container by 10%	Products meet engineering requirements in 100/100 trials	Maintains under air frieght cargo environment (temperature, pressure, humidity)	Reduce handling time from operators	Open the container quickly	Assemble the container within x amount of time	Container has x amount of space for a standard temperature monitor	Temperature monitor remains functional after one shipment	Manufacturing time is within x amount of workhours	
10 Vials	●			▽			▽									
2-8 C		●							●				○			
Last for 72-96 hours		●			●				●							
prevent breakage of vials	▽			●		●			●							
Reduced shipping cost				▽	▽		●	▽								
Reusable				○	●	▽	○	●	●					●		
Decrease handling time										●						
Safe				▽	○	●			●							
Easy to store					●											

NOW: Current Product Assesment - Customer Requirements

Row #	CREDOCUBE	*MICRO Q*	*SOFRIGAM*	*INTELLIGENT THERMAL SOLUTIONS*	CRYOPAK	COLD CHAIN TECH
1	5	5	5	5	5	5
2	5	5	5	5	5	5
3	5	5	5	5	5	5
4	5	3	2	4	3	4
5	2	1	4	2	3	1
6	5	5	4	4	3	4
7	2	3	2	2	2	2
8	4	5	4	4	4	4
9	4	3	3	4	3	2

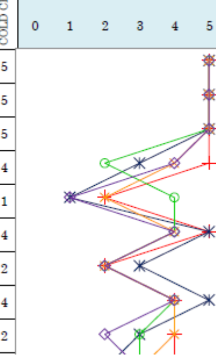
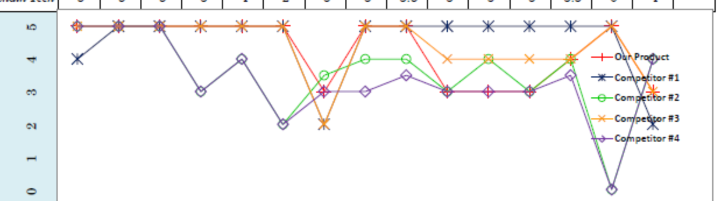


Figure 60: House of Quality Part 1

10		3%	3	2	2	0	0	0		9	Economic			●					○							●		4	2	3	3	3	3	10
11		5%	1	5	5	0	0	0			Speed of Delivery																	3	4	3	3	3	3	11
12		8%	1	0	3	0	4	4		3	Easy to carry							○			○							4	4	3	4	2	2	12
13		4%	1	0	3	0	0	4		9	Easy to open										○	●						4	4	4	4	2	4	13
14		5%	1	0	3	0	0	5		9	Easy to assemble										●		●					3	5	4	4	4	4	14
15		3%	1	0	0	5	0	0		9	Temperature Monitor													●	●			2	5	2	4	2	2	15
16		2%	5	0	0	0	0	0		9	Easy to manufacture			●												●		4	1	4	2	5	4	16

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HOW MUCH: Target	10 vials	Maintain Temperature Tmin for 72 hours	Reduce cost compared to credo cube by 5%	10 ft	Maintains dimensions under tolerance under 100lb axial load for 96	less than 1% of the material leaks out of the box when vials are cracked	10%	100% reliability rating in 100 runs	Maintains engineering requirements under air frieght cargo environment	5%	x amount of time	x amount of time	Container has x amount of space for a standard temperature monitor	Temperature monitor has a reliablity rating of 100% for 100 trials	x amount of workhours	
Max Relationship	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	
Technical Importance Rating	33.96	177.1	38.1	165.9	212.3	276.7	67.82	30.79	470.7	146.1	37.86	44.11	56.03	48.69	38.1	
Relative Weight	2%	10%	2%	9%	12%	15%	4%	2%	26%	8%	2%	2%	3%	3%	2%	
Weight Chart																
Credo Cube	5	5	5	5	5	5	3	5	5	3	3	3	4	5	3	
Competitor #1: Micro Q	4	5	5	5	5	5	2	5	5	5	5	5	5	5	2	
Competitor #2: Sofrigam	5	5	5	3	4	2	3.5	4	4	3	4	3	4	0	4	
Competitor #3: *Intelligent Thermal Solutions*	5	5	5	5	5	5	2	5	5	4	4	4	4	5	3	
Competitor #3: *Cryopak*	5	5	5	2	3	2	3	3	3.5	3	4	4	4	0	4	
Competitor #4: *Cold Chain Tech*	5	5	5	3	4	2	3	3	3.5	3	3	3	3.5	0	4	

Current Product Assesment - Engineering Specifications



Column #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

Template Revision: 0.9 Date: 4/23/2010
Christopher Battles

Figure 61: House of Quality Part 2

Table 21: Function Pugh Matrix for Holding 10 Vials

	Concept									
	Another compartment like vials	velcro it down	slot in a box	sit on top/ bottom of the box	glue/tape	in the lid	plastic pouch adhered to container	seat belted in	clamped onto kit	bigger box
Criteria	1	2	3	4	5	6	7	8	9	10
High Priority										
Protect Vials	1	1	1	1	1	1	1	1	1	D
Maintain 2-8C for 72hr	0	0	0	0	0	0	0	0	0	D
have space for temp monitor	0	0	0	2	0	0	0	0	0	D
Cost no greater than Credo by Range	0	0	0	0	0	0	0	0	0	D
Decrease dimensional weight cost	1	1	1	1	1	1	1	1	1	D
Reusable (IF high cost)	0	0	0	2	2	0	0	0	0	D
Replace secondary box	1	0	0	2	0	0	0	0	0	D
100% Reliable	0	0	0	0	0	0	0	0	0	D

Mid Priority										
96 hours	0	0	0	0	0	0	0	0	0	D
Decrease weight costs	0	0	0	0	0	0	0	2	0	D
Desired but not required										
Flexible	0	0	2	1	0	0	0	2	0	D
Total (+)	3	2	2	3	2	2	2	2	2	0
Total (-)	0	0	1	3	1	0	0	2	0	0
Total (0)	8	9	8	5	8	9	9	7	9	0

KEY	1	2	3	D
	+	-	0	Datum

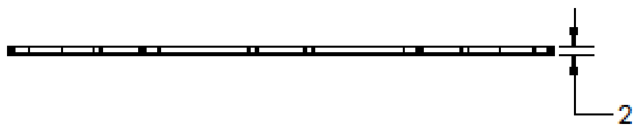
Table 22: Function Pugh Matrix for Outermost Box

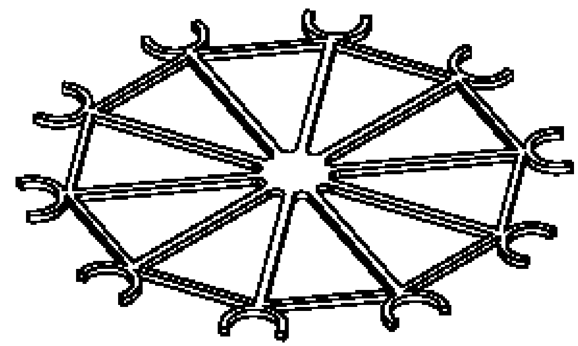
	Concepts							
	Double corrugated box packaging	Use Fedex 100lb rated boxes	Hard Plastic Boxes	Thicker corrugated box	Rigid Container (IBOX)	Aluminum Framed plastic box	Hallow aluminum box	Truss box structure
Criteria	Datum	1	2	3	4	5	6	7
Protect vials	Datum	S	S	+	+	+	+	+
Maintain 2-8C for 96 Hrs.	Datum	0	0	0	0	0	0	0
Space for temp. monitor	Datum	0	0	0	0	0	0	0
Cheaper than Credo Cube	Datum	S	-	-	-	+	-	-
Decrease dimensional weight	Datum	S	S	-	-	-	S	-
Reusable	Datum	S	+	+	+	+	+	+
Replace secondary box	Datum	0	0	0	0	0	0	0
Total (+)	Datum	0	1	2	2	3	2	2
Total (-)	Datum	0	1	2	2	1	1	2
Total (0)	Datum	0	0	0	0	2	1	0

Table 23: Function Decision Matrix for Container Shape

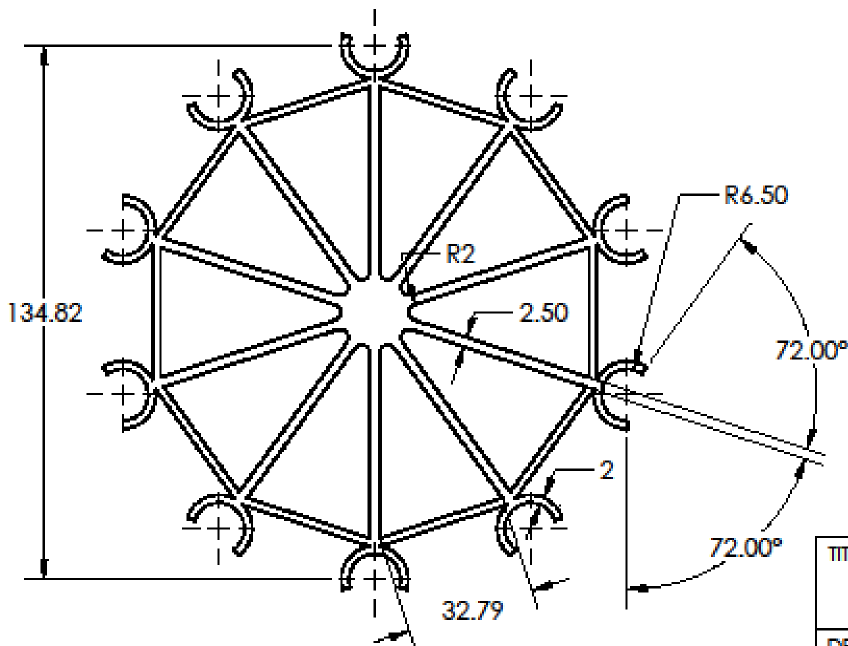
				Concept			
				Cylindrical		Square	
	Criteria	Weight (1-10)	Weight (%)	Rating	Weighted Score	Rating	Weighted Score
Reliability	Protect Vials	10	13	5	65	5	65
	Maintain 2-8C for 96hr	10	13	8	104	7	91
	Durable (low failure)	9	12	8	96	8	96
Cost	Manufacturing Cost	6	8	3	24	6	48
	Material Cost	6	8	5	40	5	40
Shipping Cost	Optimize dimensions	8	10	8	80	7	70
	Lower weight	7	9	5	45	5	45
Reusability	Reusable (100 x IF high cost)	5	6	5	30	5	30
Efficiency	Flexible	3	4	5	20	5	20
Compliant	Have space for temp monitor	3	4	5	20	5	20
Safety	Not hazardous	8	10	5	50	5	50
"Green"	Bio-degradable	2	3	5	15	5	15
	Total	77	100		589		590

APPENDIX B: DRAWING PACKET



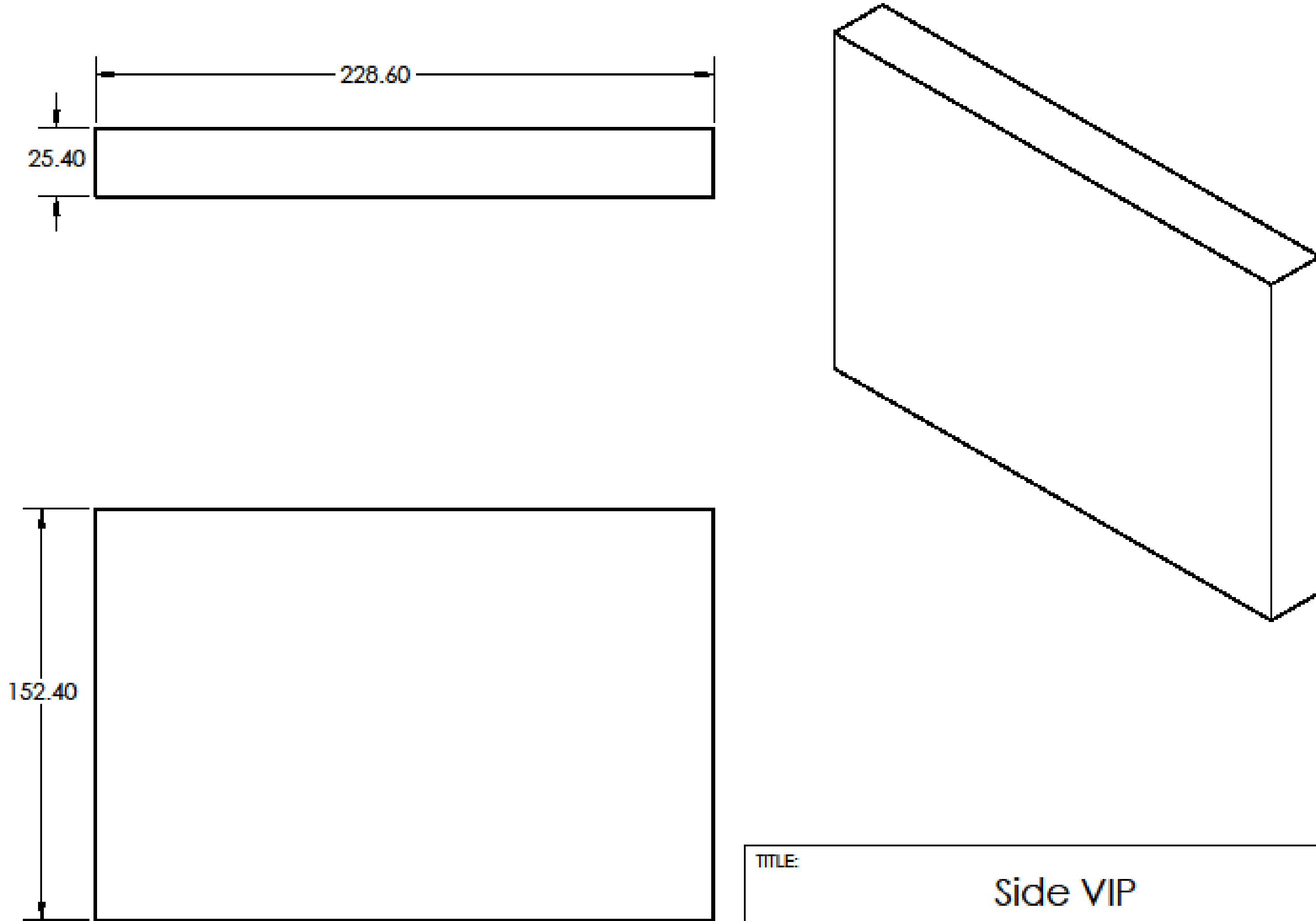


NOTE: DIMENSIONS ARE ALL SYMMETRICAL

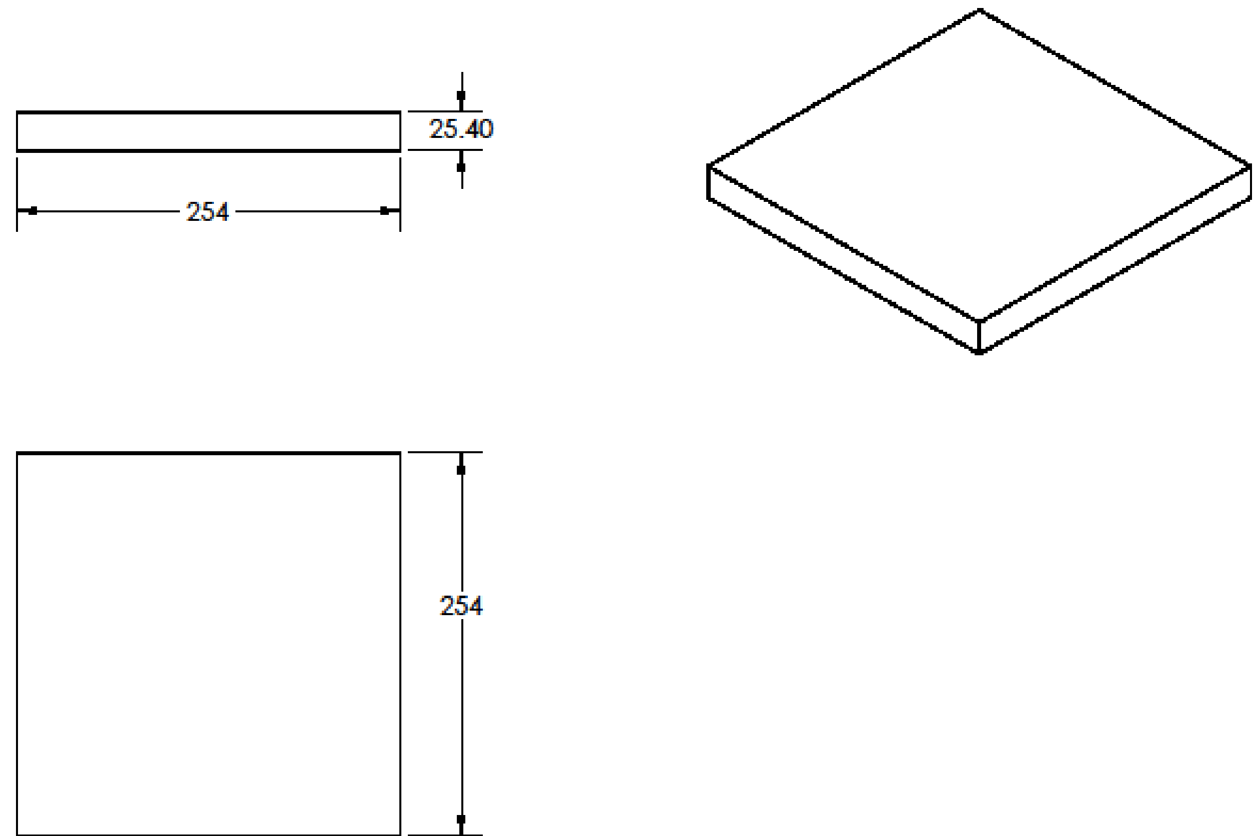


TITLE: Vial Fixture		
DRAWN BY: Yufay Chow-Yee	DWG. NO. Vial.holder_01	REV D

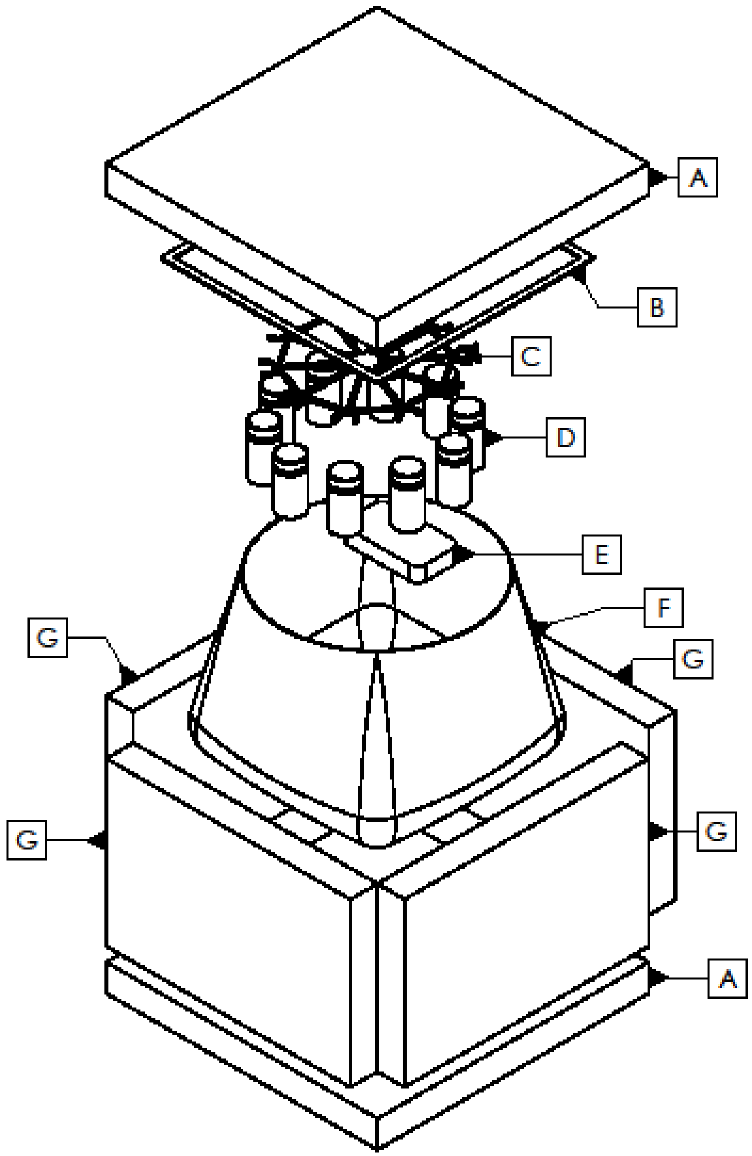
REVIEWED BY: MELINDA PHAN	SCALE: 2:3	WEIGHT: 0.05kg	SHEET 1 OF 2



TITLE: Side VIP			
DRAWN BY: Yufay Chow-Yee		DWG. NO. VIP_002	REV C
REVIEWED BY: MELINDA PHAN	SCALE: 1:2	WEIGHT: 0.15kg	Units: mm



TITLE: Lid/Bottom VIP			
DRAWN BY: Yufay Chow-Yee		DWG. NO. VIP_001	REV C
REVIEWED BY: MELINDA PHAN	SCALE: 1:4	WEIGHT: 0.28 kg	Units: mm



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
A	VIP_001	Lid and bottom Vacuum Insualted Panel 10" x 10" x 1" (254mm x 254mm x 25.4mm)	2
B	seal_001	Rubber Seal	1
C	Vial.holder_001	Rapid Prototyped Vial Fixture	1
D	Vial	Vials	10
-	PCM_Beads	Micro-Encapsulated Phase Change Material (3.9kg)	1
E	Temptale	Temperature Monitor	1
F	Bag_001	4 mil ULINE Plastic Bag	1
G	VIP_002	Side Vacuum Insulated Panels 9" x 6" x 1" (228.6mm x 152.4mm x 25.4mm)	4

NOTE: MICRO-ENCAPSULATED PCM NOT SHOWN.

TITLE: Final Concept Exploded View			
DRAWN BY: Yufay Chow-Yee		DWG. NO. assembly_01	REV D
REVIEWED BY: MELINDA PHAN	SCALE: 1:4	WEIGHT: –	SHEET 1 OF 1

APPENDIX C: LIST OF VENDORS, CONTACT INFO AND PRICING

Vacuum Insulated Paneling Vendors

Company: **Kevothermal**
(VIP Purchased From this Vender)
Price:

P/N- 10 Sets	Qty	X	Y	Z	Panel Price	Extended
VIP 1	40	6.2	5.4	1.25	$15.38	$615.10
VIP 2	20	6.65	6.65	1.25	$16.28	$325.54
						$940.64
P/N- 100 Sets	Qty	X	Y	Z	Panel Price	Extended
VIP 1	400	6.2	5.4	1.25	$5.34	$2,136.00
VIP 2	200	6.65	6.65	1.25	$7.17	$1,434.00
						$3,570.00
P/N- 1000 Sets	Qty	X	Y	Z	Panel Price	Extended
VIP 1	4000	6.2	5.4	1.25	$4.44	$17,760.00
VIP 2	2000	6.65	6.65	1.25	$5.53	$11,060.00
						$28,820.00

Contact:

Name	E-mail	Phone Number
	orders@kevothermal.com	
Sara Salazar	ssalazar@kevothermal.com	
Rodney Cheek	rcheek@kevothermal.com	(770)313-3921
		(505) 224-9373
		(505) 224-9376

Company: CSafe Global
(VIP NOT Purchased From this Vender)

Price:

P/N- 10 Sets	Qty	X	Y	Z	Panel Price	Extended
VIP	12	12	12	1	x	$300.00
						$300.00

Contact:

Name	E-mail	Phone Number
Michael Raiff	MRaiff@csafeglobal.com	19372456372

Phase Change Material Vendors

Company: **ENTROPY SOLUTIONS INC.**
(PCM NOT Purchased From this Vender)

Price:

Name	Phase Change Temperature °C	Price/Pound
PureTemp4	5	$5
PureTemp6	6	$5

Contact:

Name	E-mail	Phone Number
Eric Lindquist	elindquist@entropysolutionsinc.com	+952-374-6415

Company: **Microtek Labs**
(PCM NOT Purchased From this Vender)

Price:

Name	Phase Change Temperature °C	Price/Pound
MPCM 6	6	$4
MPCM 6D	6	$4

Contact:

Name	E-mail	Phone Number
Joe Wehrle	jw@microteklabs.com	937-236-2213 x217

Plastic Bag Vendor

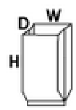
(Bags NOT Purchased From this Vender)

8 x 6 x 18" 4 Mil Gusseted Poly Bags

Enlarge

Heavy duty protection for bulky parts and equipment.

- Larger sizes for use as liners for cartons or large bins.
- Meets FDA and USDA specifications.
- Custom sizes and mil thicknesses available. Lead time 3-4 weeks.
- Also see Gusseted Pallet Covers.



MODEL NO.	SIZE W x D x H	LBS./ CTN.	PRICE PER CARTON 1	5	10	20+	QTY./ CTN.	ADD TO CART
S-17699	8 x 6 x 18"	34	$103	$98	$91	$86	500	1 ADD

Additional Info | Email Page | Request a Catalog

MATERIAL:
* Virgin polyethylene
* Acid free and archival safe
* BHT free (Butylated Hydroxy Toluene)
* Sulfur free
* Amide, Amine, & Silicon free
* Latex free

SPECIFICATIONS & APPROVALS:
* Meets ASTM D3951

MISCELLANEOUS:
* Outside dimensions are listed.
* Recyclable (#4)
* Do not store in sub-freezing temperatures.
* 3 or 4 Mil is recommended for use in a trash compactor.
* Bottom seal.
* Not treated for printing by end-user.
* Cannot use with vacuum machine. See Vacuum Bags.
* Water-resistant not waterproof. See Leakproof Bags.
* Not recommended for dry ice.
* Cannot be used for baking, cooking or boiling.
* Not microwavable.

Availability: In Stock
Unit Weight: 35 lbs.

MSDS Sheet

Catalog Page 135

Regulatory
Meets Mil-DTL-117H

Figure 62: URL of the Data for the Plastic Gusseted Bags

http://www.uline.com/Product/Detail/S-17699/Poly-Bags-Gusseted/8-x-6-x-18-4-Mil-Gusseted-Poly-Bags?model=S-17699

Weather Stripping Vendor

(Weather Stripping NOT Purchased From this Vender)

Rubber Bulb Seal

EPDM, 3/8" Overall Width, 3/8" Overall Height

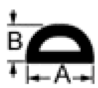
Length, ft.
10
20
50
Other

Each

ADD TO ORDER

1-99 Ft. $1.11
100 or more $0.94
1142A71

1 each of 10 ft. added to your order 04/29/14.



Overall Width (A)	3/8"
Overall Height (B)	3/8"
Material	EPDM
Additional Specifications	Style 10 Plain Back

Use where a tight seal is needed. Cut to length with scissors or a knife. Install plain back with staples, tacks, or screws (not included); silicone-based adhesive can also be used for plain-back silicone.

EPDM Seals—Good resistance to weathering. Durometer hardness is A70, unless noted. Temperature range is –30° to 200° F. Color is black.

To Order: Please specify length from those listed below. The last length listed is the maximum continuous length.

Figure 63: URL for the website for this Specific Item

http://www.mcmaster.com/#1142a71/=rra69g

Corrugated Box Vendor

(Boxes Purchased From this Vender)

9 x 9 x 6" Corrugated Boxes

Enlarge

200 LB. TEST

High quality corrugated boxes in a large selection of sizes.

- Use to pack, ship and store products.
- Easy to set up, load and close.
- Shipped flat for freight savings.

SOLD IN BUNDLE QUANTITIES

MODEL NO.	INSIDE DIM L x W x H	PRICE PER BOX					BUNDLE/ BALE QTY.	LBS./ BNDL.	ADD TO CART
		25	100	250	500	1,000+			
S-4309	9 x 9 x 6"	$.63	$.60	$.51	$.48	$.46	25 / 900	13	25 ADD

Additional Info | Email Page | Request a Catalog

```
200# TEST VS 32 ECT (EDGE CRUSH TEST):
 * 200# test: 30-50% stronger bursting strength.
              Recommended by UPS for shipping up to 40 lbs.
 * 32 ECT: Recommended by UPS for shipping up to 30 lbs.
Pound test refers to bursting strength:
 * 200# test boxes withstand 200 lbs/sq.in. of side wall
   pressure before bursting.
ECT refers to stacking strength:
 * 32 ECT boxes withstand 32 lbs/linear inch of stacking
   weight before crushing.
 * An alternative for lightweight shipments.

Closest equivalents:
 * 32 ECT - 200# test
 * 42 ECT - 200# test DW
 * 44 ECT - 275# test
 * 48 ECT - 275# test DW
 * 51 ECT - 350# test DW
 * 71 ECT - 500# test DW
 * 82 ECT - 600# test DW

BOX STRENGTH GUIDELINES: (Maximum weight per box)

                          FIBER BOX      UPS
                           HANDBOOK   GUIDELINES
   32 ECT Single Wall      65 lbs       30 lbs
   200# Single Wall        65 lbs       40 lbs
   275# Single Wall        95 lbs       65 lbs
   350# Single Wall       120 lbs       80 lbs
   200# Double Wall        80 lbs       60 lbs
   275# Double Wall       100 lbs       80 lbs
   350# Double Wall       120 lbs      100 lbs
   500# Double Wall       160 lbs      140 lbs

GENERAL BOX SPECIFICATIONS AND REGULATIONS:
 * All boxes open along the length (first dimension).
 * Seams are glued.
FLUTE:
 * Definition: Wave shapes pressed into the middle of the
   corrugated wall of the box.  Most of Uline single wall
   boxes are C-flute.
 * Approximate thickness:
   A flute 3/16"
   C flute 9/64"
   B flute 3/32"
   E flute 3/64"
```

Availability: In Stock
Unit Weight: 0.50 lbs.

MSDS Sheet

Catalog Page 6

Country of Origin: USA

Regulatory
ASTM D5118
ASTM D3951

Figure 64: URL to the Website of this Item:

http://www.uline.com/Product/Detail/S-4309/Corrugated-Boxes-200-Test/9-x-9-x-6-Corrugated-Boxes

APPENDIX D: VENDOR SUPPLIED COMPONENT SPECIFICATIONS AND DATA SHEETS

Vacuum Insulation Paneling

Kevothermal/Nanopore

NANOPORE INSULATION

NanoPore™ Vacuum Insulation Panel (VIP)

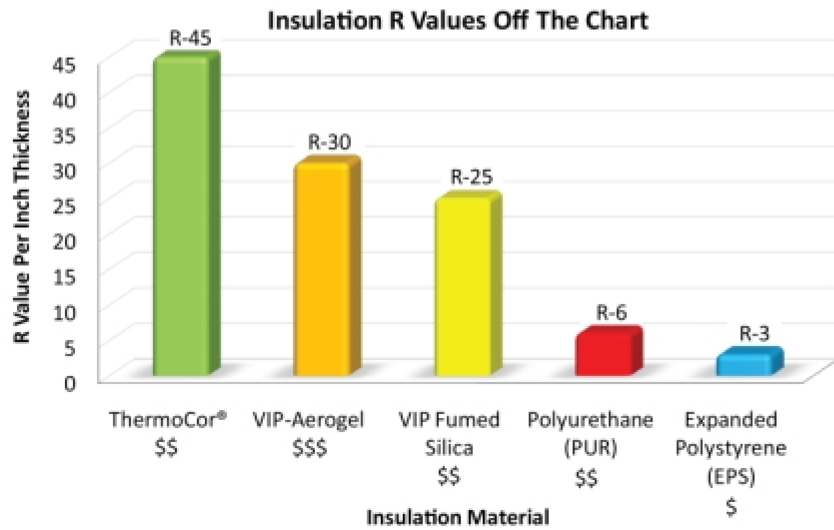
Technical Data Sheet for Silica-Based VIP

	US	Metric
Length[1], 36" (914 mm) max	1" – 36"	25.4 mm – 914 mm
Width[1], 24" (610 mm) max	1" – 24"	25.4 mm – 610 mm
Thickness[2]	1/4" – 1.5"	6 mm – 38.1 mm
Thermal Resistivity[4]/Conductivity[3]	R36 +/- 4 per inch	0.004 +/- 0.0004 W/m.K
Continuous Working Temperature[5]	-460 to 149 °F	-273 to 65 °C
Thermal Shrinkage	<1% @ 248 °F	<1% @ 120 °C
Density[6]	10.0 – 11.2 lb/ft³	160 - 180 kg/m³
Compressive Strength (@ 5% strain)	17 psi	120 kPa
Compressive Modulus (@ 5% strain)	214 psi	1500 kPa
Resistance to chemicals	Excellent	
Recyclability	Excellent	
Lifetime[7]		

[1] Standard Tolerance for length and width is +/- 3mm.
[2] Standard Tolerance for thickness is +/- 1.5mm
[3] Center-of-Panel measurement at mean temperature 10°C in accordance with ASTM C518
[4] R-Value/inch = $(\text{BTU in/ft}^2\text{hr°F})^{-1}$
[5] Upper limit is fixed by the barrier material used, not the core's thermal stability.
[6] Compressed core density excluding the barrier films at < 10 mbar
[7] Lifetime is application dependant. To obtain an estimate or understanding of lifetime, please consult NanoPore Insulation.

Revision 2.1
5 May 2011

Thermocor/Csafe



ThermoCor offers R Values of 45 per inch thickness. This is ideal for shipping highly valuable temperature-sensitive products which is 10 times greater than traditional insulating materials.
Incorporates features that significantly retard all four basic heat transfer mechanisms: conduction, conduction through fluids and gases, radiation and convection.
1 inch = R45 or K of 0.022

Renewable Phase Change Technology

PureTemp™ Thermal Energy Storage Materials

PureTemp thermal energy storage materials offer new levels of performance in storing or releasing large quantities of thermal energy at any given temperature. Our proprietary formulations and patented manufacturing processes yield superior quality phase change materials at cost effective prices.

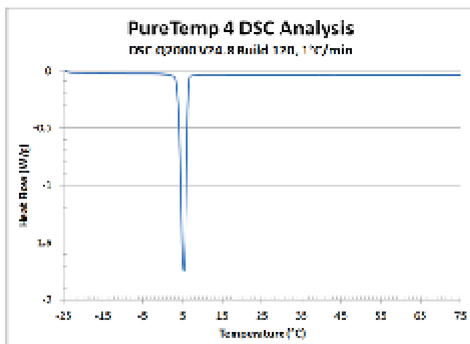
Some key properties:

- Thermal energy storage capacities which average 200 J/g
- Over 200 unique, engineered phase change transition temperatures between -40˚C and 150˚C
- Consistent, repeatable performance over thousands of thermal (melt/solidify) cycles
- 100% renewable – produced from agricultural sources, not petroleum
- Readily biodegradable and non-toxic

PureTemp 4 Technical Information

Appearance	Clear liquid, waxy solid
Melting Point	5˚C
Heat storage capacity	195 J/g
Density	0.88 g/ml
Specific heat liquid	2.86 J/g˚C
Specific heat solid	2.44 J/g˚C
Solubility in water	Negligible
Stability	Stable under normal conditions

Typical physical properties are listed in the table above.



Entropy Solutions, Inc.
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Tel: +1-952-941-0306 Email: info@puretemp.com
www.puretemp.com

Renewable Phase Change Technology

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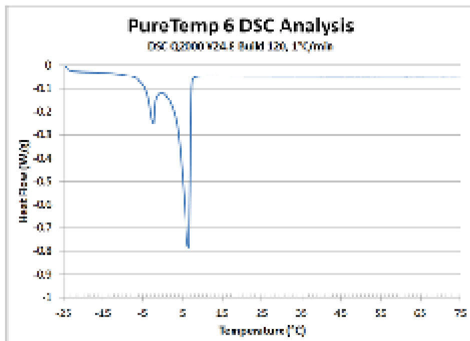
- Over 200 unique, engineered phase change transition temperatures between -40˚C and 150˚C
- Consistent, repeatable performance over thousands of thermal (melt/solidify) cycles
- 100% renewable – produced from agricultural sources, not petroleum
- Readily biodegradable and non-toxic

PureTemp 6 Technical Information

Appearance	Clear liquid, waxy solid
Melting Point	6˚C
Heat storage capacity	170 J/g
Density	0.86 g/ml
Specific heat liquid	1.73 J/g˚C
Specific heat solid	1.56 J/g˚C
Solubility in water	Negligible
Stability	Stable under normal conditions

Typical physical properties are listed in the table above.



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MPCM 6

Microencapsulated Phase Change Material

Phase Change: 6°C , 42.8°F

DESCRIPTION

Microencapsulated phase change materials (MicroPCMs) are very small bi-component particles consisting of a core material – the PCM - and an outer shell or capsule wall. PCMs are low melting materials with melt points in the range of -30°C to 55°C, that can absorb and release large amounts of heat. The capsule wall is an inert, stable polymer or plastic.

APPLICATIONS

Microencapsulated PCMs are used to regulate temperatures and for heat storage in a variety of applications.

A primary use of the microPCM products is in the coating of fabrics and foams for the textile industry. The coated materials have broad applications for use in various wearing apparel such as inner and outer garments, gloves and footwear. These end-use products containing microPCMs work by absorbing the body's excess heat, storing that heat, and releasing it back to the body as needed.

Microencapsulated PCMs are also finding wide spread applications in several other areas, including in:

- **Electronics** - for cooling electrical components in computers, increasing duty cycles in lasers, and helping maintain constant temperatures for scientific instrumentation and military equipment used in the field.
- **Building Materials** – to increase the energy efficiency of residential and commercial buildings. The materials are being used in combination with radiant heat and solar energy to extend the heating and cooling efficiencies of these systems. PCMs are also being incorporated in plasters, fiberboards, tiles, and insulation.
- **Storage Solutions** – to protect food, beverages, medical products, and temperature-sensitive chemicals in transit.

PROPERTIES

The MPCM 6 product exhibits the following general properties:

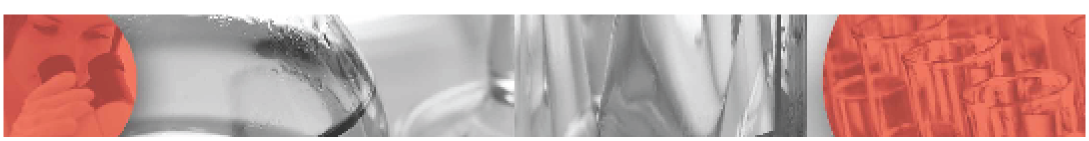
Typical Properties	
Appearance	White to slightly off-white color
Form	Wet cake (70% Solids, 30% Water)
Capsule composition	85-90% wt.% PCM 10-15 wt.% polymer shell
Core material	Paraffin
Particle size (mean)	17-20 micron
Melting point	6°C (43°F)
Heat of Fusion	157 - 167 J/g
Specific Gravity	0.9
Temperature Stability	Extremely stable – less than 1% leakage when heated to 250°C
Thermal Cycling	Multiple

PACKAGING

This product is generally shipped in 50-gallon fiber drums of 250 pounds net weight (175 pounds nominal dry weight). Sample quantities may be ordered for customers requiring smaller amounts of product.

HEALTH AND SAFETY

The product is classified as non-hazardous. Please refer to the Material Safety Data Sheet (MSDS) for necessary safety and handling precautions for this product.



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MPCM 6D

Microencapsulated Phase Change Material

Phase Change: 6°C , 42.8°F

DESCRIPTION

Microencapsulated phase change materials (MicroPCMs) are very small bi-component particles consisting of a core material – the PCM - and an outer shell or capsule wall. PCMs are low melting materials with melt points in the range of -30°C to 55°C, that can absorb and release large amounts of heat. The capsule wall is an inert, stable polymer or plastic.

APPLICATIONS

Microencapsulated PCMs are used to regulate temperatures and for heat storage in a variety of applications.

A primary use of the microPCM products is in the coating of fabrics and foams for the textile industry. The coated materials have broad applications for use in various wearing apparel such as inner and outer garments, gloves and footwear. These end-use products containing microPCMs work by absorbing the body's excess heat, storing that heat, and releasing it back to the body as needed.

Microencapsulated PCMs are also finding wide spread applications in several other areas, including in:

- **Electronics** - for cooling electrical components in computers, increasing duty cycles in lasers, and helping maintain constant temperatures for scientific instrumentation and military equipment used in the field.
- **Building Materials** – to increase the energy efficiency of residential and commercial buildings. The materials are being used in combination with radiant heat and solar energy to extend the heating and cooling efficiencies of these systems. PCMs are also being incorporated in plasters, fiberboards, tiles, and insulation.
- **Storage Solutions** – to protect food, beverages, medical products, and temperature-sensitive chemicals in transit.

PROPERTIES

The MPCM 6D product exhibits the following general properties:

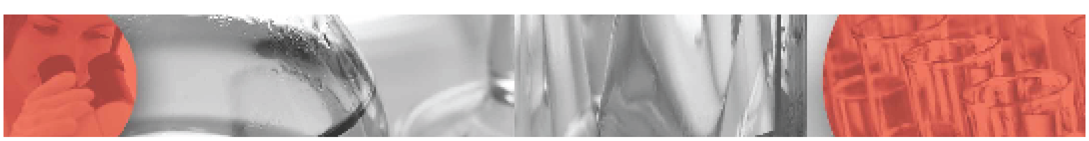
Typical Properties	
Appearance	White to slightly off-white color
Form	Dry powder
Capsule composition	85-90% wt.% PCM 10-15 wt.% polymer shell
Core material	Paraffin
Particle size (mean)	17-20 micron
Melting point	6°C (43°F)
Heat of Fusion	157 - 167 J/g
Specific Gravity	0.9
Temperature Stability	Extremely stable – less than 1% leakage when heated to 250°C
Thermal Cycling	Multiple

PACKAGING

This product is generally shipped in 50-gallon fiber drums of 140 pounds net weight. Sample quantities may be ordered for customers requiring smaller amounts of product.

HEALTH AND SAFETY

The product is classified as non-hazardous. Please refer to the Material Safety Data Sheet (MSDS) for necessary safety and handling precautions for this product.

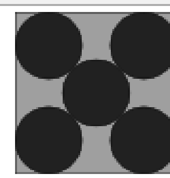


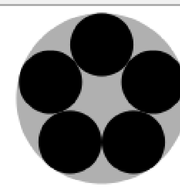
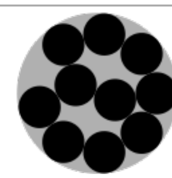
APPENDIX E: DETAILED SUPPORTING ANALYSIS

Optimal Shape Analysis Calculations

There were five three dimensional prisms considered in optimization of space: Cubic, Rectangular, Cylindrical, Spherical and Hexagonal. Calculations assume a standard 10mL vial size of 23mm diameter and 43mm height. Dimensions for each prism were calculated from either two rows of five vials or one row of ten vials.

The following circle packing theorems were also assumed:

Number of circles	Square size (side length)	dn	Number density	Figure
5	$2+2\sqrt{2}$ ≈ 4.828...	$\frac{1}{2}\sqrt{2}$ ≈ 0.707...	0.215...	

Number of unit circles	Enclosing circle radius	Density	Optimality	Diagram
5	$1+\sqrt{2(1+\frac{1}{\sqrt{5}})}$ ≈ 2.701...	0.6854...	Proved optimal by Graham in 1968.	
10	3.813...	0.6878...	Proved optimal by Pirl in 1969.	

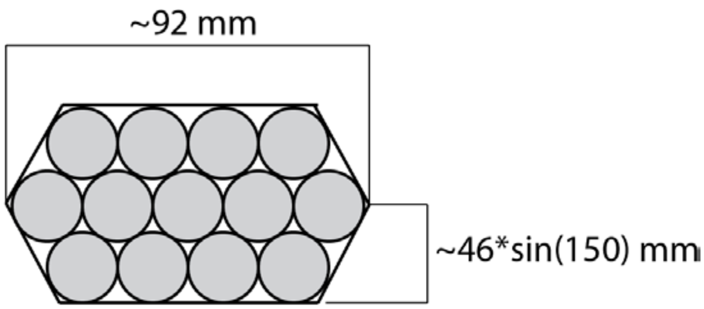
Sample Calculation for 5x2 vial Cylindrical Prism
Vial Radius = 23/2 mm
Enclosing Circle Radius=?

$$\frac{Inner\ Circle\ Radius}{Enclosing\ Circle\ Radius} = \frac{1}{2.701} = \frac{11.5mm}{x}$$

x = 4.46 mm
Diameter of Container = 8.52 mm
Height of Container = 43mm*2= 96mm

$$Surface\ Area = [2 * (\pi * r^2)] + (2 * \pi * r * h)$$
$$= [2 * (\pi * 4.46mm^2)] + (2 * \pi * 4.46mm * 96mm)$$
$$Volume = (\pi * r^2) * h$$
$$= (\pi * 4.46mm^2) * 96mm$$

Sample Calculation for 10x1 vial Hexagonal Prism



Height of Container = 43mm

$$Surface\ Area = \left[2 * \left(\frac{a+b}{2}\right) * l\right] + [h * (2a + 4c)]$$
$$= \left[2 * \left(\frac{69mm + 92mm}{2}\right) * 46\,sin(150)\,mm\right] + [43mm * (2 * 69mm + 4 * 46mm)]$$
$$Volume = \left(\frac{a+b}{2}\right) * l * h$$
$$= \left(\frac{69mm + 92mm}{2}\right) * 46\,sin(150)\,mm * 43mm$$

Analysis for TEC

-VIP only mode of heat transfer is radiation
-2 radiation shields, one on each side of the panels

$$q_{radiation} = \frac{\sigma(T_1^4 - T_2^4)}{R_{total}}$$

$$R_{total} = \sum Resistors$$
$$= \frac{1-\epsilon_1}{\epsilon_1 A_1} + \frac{1}{A_1 F_{1a}} + \frac{1-\epsilon_{1a}}{\epsilon_{1a} A_{1a}} + \frac{1-\epsilon_{ab}}{\epsilon_{ab} A_{ab}} + \frac{1}{A_a F_{ab}} + \frac{1-\epsilon_{ab}}{\epsilon_{ab} A_{ab}} + \frac{1-\epsilon_{b2}}{\epsilon_{b2} A_{b2}} + \frac{1}{A_2 F_{b2}} + \frac{1-\epsilon_2}{\epsilon_2 A_2}$$

$$R_{total} = 38.27\ \frac{1}{m^2}$$

$$T_1(\text{Outside Temp}) = 28°C = 301K$$
$$T_2(\text{Payload Temp} = 5°C = 278K$$
$$\sigma = 5.78 \text{ x } 10^{-8} \frac{W}{m^2K^4} (\text{Stefan} - \text{Boltzmann Constant})$$

$$q_{radiation} = \frac{5.78 \text{ x } 10^{-8} \frac{W}{m^2K^4} (301K^4 - 278K^4)}{38.27 \ \frac{1}{m^2}}$$

$$\mathbf{q_{radiation} = 3.15 \ Watts}$$

$$\text{Coefficient of Performance} = \frac{Q_{in}}{P_{in}} = \frac{\text{What you get}}{\text{What you pay for}}$$
$$P_{in} = \frac{3.15 \text{ Watts}}{0.4 \text{ (lower COP)}}$$
$$P_{in} = 7.9 \text{ Watts}$$
$$P = I * V \ \rightarrow \ I = \frac{P}{V}$$
$$I = \frac{96\text{Hrs} * 7.9\text{Watts}}{12\text{VDC}}$$
$$I = 63.2 \text{ Amp} - \text{Hours @ 12VDC}$$

Our concepts were analyzed with basic heat transfer equations. Conservative estimates were made for the assumptions. For instance, the only method of heat entering the packaging is through the vacuum insulated paneling. In addition, the thermal conductivity provided by the vendor is for heat entering the panels perpendicularly, toward the center of the panels. In reality, heat enters the packaging from all directions and angles as well as from the edges where the VIP was not designed to insulate as effectively as the middle.

Another assumption was estimating the outside surface temperature was at 35°C. This assumption was conservative since 35°C were estimated for 100 hours. The time required for the PCM was increased to 100 hours in order to compensate for some minor loses not accounted for in our calculations.

For the Thermoelectric / PCM combination, an optimization table was created. The type of insulation used for this concept is vacuumed insulated paneling manufactured by Nanopore. In this table, the goal was to obtain the optimal ratio of battery capacity and amount of PCM. From the table, 100% PCM gave the smallest and lightest configuration. Therefore having a thermoelectric system will not satisfy all customer requirements. The calculations below show the head load according to the dimensions of this concept. The thermoelectric system will maintain 2-8°C for over 96 hours, but it is not the best solution to this problem. Therefore, the concept of using a combination of a thermoelectric system with PCM was dismissed.

Thermoelectric / PCM Combination Calculations

$$q_{load} = \frac{T_{ambient} - T_{inside}}{\frac{L}{k * A_{surface}}}$$

q_{load} = Amount of heat entering the system (package) through the VIP

$T_{ambient}$ = Outside surface temperature

T_{inside} = Inside air temperature

L = Thickness of insulation

k = Thermal Conductivity

$A_{surface}$ = Total external surface area

$T_{ambient} = 35°C$

$T_{inside} = 5°C$

L = 1.00 in = 0.0254m

$k = 0.004 \frac{W}{m * K}$

$A_{surface}$ = 2*(0.254m * 0.254m) + 4*(0.254m * 0.203m) = 0.4955 m^2

$$q_{load} = \frac{35°C - 5°C}{\left[\frac{0.0254m}{0.004 \frac{W}{m * K} * 0.4955\ m^2}\right]}$$

$q_{load} = 1.58 \text{ Watts}$

$$m_{PCM} = \frac{q_{load} * \Delta t}{h_{lf}}$$

m_{PCM} = Amount of PCM required to counter the heat load

h_{lf} = Latent heat of fusion

$q_{load} = 1.58 \text{ Watt}$

$\Delta t = 100 \text{ hours}$

$h_{lf} = 195 \frac{kJ}{kg}$

$$m_{PCM} = \frac{1.58 \text{ Watts} * 100 \text{ Hours} * \frac{3600 \text{ seconds}}{1 \text{ hour}}}{195 \frac{kJ}{kg} * \frac{1000 \text{ J}}{1 \text{ kJ}}}$$

$m_{PCM} = 2.92 \text{ kg}$ @ 100% PCM

$$\text{Coefficient of Performance} = \frac{q_{in}}{P_{in}} = \frac{\text{What you get}}{\text{What you pay for}}$$

$q_{in} = q_{load}$ = Amount of heat entering the system (package)

P_{in} = Power required from the thermoelectric system

$q_{in} = 1.58 \text{ Watts}$

Coefficient of Performance (COP) = 0.4

$$P_{in} = \frac{1.58 \text{ Watts}}{0.4 \text{ (lower COP)}}$$

$P_{in} = 4.0$ Watts

$$\text{Battery Capacity} = \frac{P * \Delta t}{V}$$

P = Power (Watts)

Δt= Time that battery should last

V = Voltage (volts)

$$I = \frac{96\text{Hrs} * 4.0\ \text{Watts}}{12\text{VDC}}$$

$I = 32$ Amp − Hours @ 12VDC

Calculations for Negative PCM

$$q_{load} = \frac{T_{ambient} - T_{inside}}{\frac{L}{k * A_{surface}}}$$

$T_{ambient} = 35°C$

$T_{inside} = 5°C$

L = 1.00 in = 0.0254m

$k = 0.004 \frac{W}{m * K}$

$A_{surface} = 2*(0.211m * 0.211m) + 4*(0.211m * 0.145) = 0.211m^2$

$$q_{load} = \frac{35℃ - 5℃}{\left[\frac{0.0254m}{0.004\ \frac{W}{m\ *K}\ *\ 0.211\ m^2}\right]}$$

$q_{load} = 1.00$ Watts

$$m_{PCM} = \frac{q_{load}\ *\ \Delta t}{h_{lf}}$$

$q_{load} =$ 1.00 Watt

$\Delta t = 100$ hours

$h_{lf} = 195\ \frac{kJ}{kg}$

$$m_{PCM} = \frac{1.00\ \text{Watts}\ *\ 100\ \text{Hours} * \frac{3600\ \text{seconds}}{1\ \text{hour}}}{195\ \frac{kJ}{kg} * \frac{1000\ J}{1\ kJ}}$$

$m_{PCM} = 1.81$ kg

Calculations for Flexible PCM

$$q_{load} = \frac{T_{ambient} - T_{inside}}{\frac{L}{k * A_{surface}}}$$

$T_{ambient} = 35℃$

$T_{inside} = 5℃$

$L = 1.00$ in $= 0.0254m$

$k = 0.004 \frac{W}{m * K}$

$A_{surface} = 2*(0.292m * 0.254m) + 2*(0.254m * 0.051) + 2*(0.292m * 0.051) = 0.232m^2$

$$q_{load} = \frac{35°C - 5°C}{\left[\frac{0.0254m}{0.004 \frac{W}{m * K} * 0.232 \, m^2}\right]}$$

$q_{load} = 1.10$ Watts

$$m_{PCM} = \frac{q_{load} * \Delta t}{h_{lf}}$$

$q_{load} = 1.10$ Watt

$\Delta t = 100$ hours

$h_{lf} = 195 \frac{kJ}{kg}$

$$m_{PCM} = \frac{1.10 \text{ Watts} * 100 \text{ Hours} * \frac{3600 \text{ seconds}}{1 \text{ hour}}}{195 \frac{kJ}{kg} * \frac{1000 \text{ J}}{1 \text{ kJ}}}$$

$m_{PCM} = 2.02$ kg

Calculations for Macro-Encapsulated PCM

$$q_{load} = \frac{T_{ambient} - T_{inside}}{\frac{L}{k * A_{surface}}}$$

$T_{ambient} = 35°C$

$T_{inside} = 5°C$

$L = 1.00 \text{ in} = 0.0254m$

$k = 0.004 \frac{W}{m * K}$

$A_{surface} = 2*(0.254m * 0.254m) + 4*(0.254m * 0.152) = 0.284m^2$

$$q_{load} = \frac{35°C - 5°C}{\left[\frac{0.0254m}{0.004 \frac{W}{m * K} * 0.284 m^2}\right]}$$

$q_{load} = 1.34 \text{ Watts}$

$$m_{PCM} = \frac{q_{load} * \Delta t}{h_{lf}}$$

$q_{load} = 1.34 \text{ Watt}$

$\Delta t = 100 \text{ hours}$

$h_{lf} = 195 \frac{kJ}{kg}$

$$m_{PCM} = \frac{1.10 \text{ Watts} * 100 \text{ Hours} * \frac{3600 \text{ seconds}}{1 \text{ hour}}}{195 \frac{kJ}{kg} * \frac{1000 J}{1 kJ}}$$

$m_{PCM} = 2.48 \text{ kg}$

$$m_{Bead\ PCM} = m_{PCM} * \text{Bead efficiency} + m_{PCM}$$

$m_{Bead\ PCM}$ = Total mass including polymer coating on beads

Bead efficiency = Percentage of mass that is the polymer's mass

Bead efficiency = 15% = 0.15

$$m_{\text{Bead PCM}} = 2.48\text{kg} * 0.15 + 2.48\text{kg}$$

$m_{\text{Bead PCM}} = 2.88\text{kg}$

Table 24: TEC to PCM Optimization

			PCM Weight									
			Hours	72	75	78	81	84	87	90	93	96
			Weight (kg)	2.3	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0
TEC Battery Weight	Weight (kg)	Hours	% overall	75.0%	78.1%	81.3%	84.4%	87.5%	90.6%	93.8%	96.9%	100.0 %
	30.50	24	25.0%	32.8	32.8	32.9	33.0	33.1	33.2	33.3	33.4	33.5
	31.75	21	21.9%	34.0	34.1	34.2	34.3	34.4	34.5	34.6	34.7	34.8
	24.95	18	18.8%	27.2	27.3	27.4	27.5	27.6	27.7	27.8	27.9	27.9
	18.14	15	15.6%	20.4	20.5	20.6	20.7	20.8	20.9	21.0	21.0	21.1
	17.69	12	12.5%	19.9	20.0	20.1	20.2	20.3	20.4	20.5	20.6	20.7
	14.06	9	9.4%	16.3	16.4	16.5	16.6	16.7	16.8	16.9	17.0	17.1
	6.35	6	6.3%	8.6	8.7	8.8	8.9	9.0	9.1	9.2	9.3	9.4
	4.54	3	3.1%	6.8	6.9	7.0	7.1	7.2	7.3	7.3	7.4	7.5
	0.00	0	0.0%	2.3	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0

The table above shows the total weights of the thermoelectric system combined with PCM. The spaces in green are the optimized weights which concluded in 100% PCM. The column weight (kg) shows the weight of a battery that would satisfy the TEC system in this optimization. The next column, labeled hours identifies how long the TEC system will meet customer specifications. The column and row labeled % overall shows how much that component is contributing to the 96 hour customer specification. The row labeled weight(kg) under PCM weight shows the amount of weight that will last for the specified amount of hours. For instance, if we use the upper left corner box highlighted in green, a battery weighing 30.5 kg is required with 2.3 kg of PCM.

APPENDIX F: GANTT CHART

Table 25: Detailed Gantt Chart with Tasks Only

ID	WBS	Task Name	Start	Finish	Duration	Dec 29, '13 Jan 5, '14 Jan 12, '14 Jan
1	**1**	**Team Formation**	**Wed 1/8/14**	**Thu 1/16/14**	**6 days**	
2	1.1	Project Preference Form	Wed 1/8/14	Wed 1/8/14	0 days	**1/8**
3	1.2	Intro Letter to Sponsor	Tue 1/14/14	Tue 1/14/14	0 days	**1/14**
4	1.3	Team Contract	Thu 1/16/14	Thu 1/16/14	0 days	**1/16**
5	**2**	**Define Project**	**Thu 1/23/14**	**Tue 2/25/14**	**23 days**	
6	2.1	QFD	Thu 1/30/14	Thu 1/30/14	0 days	
7	2.2	Project Proposal	Fri 1/31/14	Fri 1/31/14	0 days	
8	2.3	Problem Statement	Thu 1/23/14	Thu 1/23/14	0 days	
9	2.4	Meeting with sponsor	Thu 2/6/14	Sat 2/8/14	3 days	
10	2.5	Background research	Mon 2/10/14	Tue 2/25/14	12 days	
11	**3**	**Idea Generation/Selection**	**Tue 2/11/14**	**Mon 3/3/14**	**15 days**	
12	3.1	Prepare conceptual models	Tue 2/11/14	Tue 2/18/14	6 days	
13	3.2	Decision Matrix	Tue 2/25/14	Tue 2/25/14	0 days	

ID	WBS	Task Name	Start	Finish	Duration	Dec 29, '13	Jan 5, '14	Jan 12, '14	Jan
14	3.3	Conceptualize Solutions	Wed 2/19/14	Mon 3/3/14	9 days				
15	4	Concept Proposal Presentation to Sponsor	Tue 3/11/14	Tue 3/11/14	0 days				
16	**5**	**Prelim Analysis**	**Thu 2/13/14**	**Tue 3/4/14**	**14 days**				
17	5.1	Thermoelectric cooler size chosen	Thu 2/13/14	Mon 3/3/14	13 days				
18	5.2	Battery Size Determined	Thu 2/13/14	Mon 3/3/14	13 days				
19	5.3	Amount of PCM needed for payload	Thu 2/13/14	Mon 3/3/14	13 days				
20	5.4	Start presentation for CDR	Thu 2/13/14	Mon 3/3/14	13 days				
21	5.5	Concept Models	Thu 2/13/14	Mon 3/3/14	13 days				
22	5.6	FMEA	Thu 2/13/14	Mon 3/3/14	13 days				
23	**5.7**	**Prelim Design Review PDR**	**Mon 2/24/14**	**Tue 3/4/14**	**7 days**				
24	5.7.1	update background section	Mon 2/24/14	Thu 2/27/14	4 days				
25	5.7.2	update method of approach	Mon 2/24/14	Thu 2/27/14	4 days				
26	5.7.3	Gantt Chart	Mon 2/24/14	Thu 2/27/14	4 days				

ID	WBS	Task Name	Start	Finish	Duration	Dec 29, '13	Jan 5, '14	Jan 12, '14	Jan
27	5.7.4	Decision matrix	Mon 2/24/14	Thu 2/27/14	4 days				
28	5.7.5	Identifiy Prelim plans for construction and testing	Mon 2/24/14	Thu 2/27/14	4 days				
29	5.7.6	Create ideation section	Mon 2/24/14	Thu 2/27/14	4 days				
30	5.7.7	PDR Presentation	Tue 3/4/14	Tue 3/4/14	1 day				
31	**6**	**Design Analysis/Testing**	**Wed 4/2/14**	**Thu 5/29/14**	**42 days**				
32	**6.1**	**Design Analysis**	**Wed 4/2/14**	**Thu 4/17/14**	**12 days**				
33	**6.1.1**	**Detailed Analysis of Required PCM**	**Wed 4/2/14**	**Wed 4/2/14**	**1 day**				
34	6.1.1.1	Optimization tool with dimension output	Wed 4/2/14	Wed 4/2/14	1 day				
35	6.1.1.2	Optimization tool with heat load output	Wed 4/2/14	Wed 4/2/14	1 day				
36	6.1.1.3	Function that gives mass of pcm required based on the Q	Wed 4/2/14	Wed 4/2/14	1 day				
37	**6.1.2**	**Perform and Complete TEC/PCM Optimization Analysis**	**Wed 4/2/14**	**Thu 4/10/14**	**7 days**				
38	**6.1.2.1**	**Excel Sheet for TEC/PCM optimization**	**Wed 4/2/14**	**Thu 4/10/14**	**7 days**				
39	6.1.2.1.1	Input is q, time ->PCM(kg) vs power needed	Wed 4/2/14	Thu 4/10/14	7 days				

ID	WBS	Task Name	Start	Finish	Duration	Dec 29, '13	Jan 5, '14	Jan 12, '14	Jan
40	6.1.2.1.2	TEC Selection with module COP, battery selection	Wed 4/2/14	Thu 4/10/14	7 days				
41	6.1.2.1.3	Weight comparison	Wed 4/2/14	Thu 4/10/14	7 days				
42	**6.1.3**	**Identify and Select Vendors**	**Wed 4/2/14**	**Thu 4/17/14**	**12 days**				
43	6.1.3.1	Obtain quotes for PCM encapsulation	Wed 4/2/14	Thu 4/17/14	12 days				
44	6.1.3.2	Obtain quotes for PCM	Wed 4/2/14	Thu 4/17/14	12 days				
45	6.1.3.3	Obtain quotes for VIP	Wed 4/2/14	Thu 4/17/14	12 days				
46	**6.1.4**	**Detailed Analysis of VIP dimensions**	**Fri 4/11/14**	**Thu 4/17/14**	**5 days**				
47	6.1.4.1	Optimization of VIP thickness and PCM	Fri 4/11/14	Thu 4/17/14	5 days				
48	**6.2**	**Select Minimum Viable Product (MVP)**	**Fri 4/11/14**	**Thu 4/17/14**	**5 days**				
49	6.2.1	Iterate Decision Matrix	Fri 4/11/14	Thu 4/17/14	5 days				
50	6.2.2	Finalize all material selection	Fri 4/11/14	Thu 4/17/14	5 days				
51	**6.3**	**Baseline Testing**	**Mon 5/5/14**	**Thu 5/29/14**	**19 days**				
52	6.3.1	Credo Cube Latent Head Verification	Mon 5/5/14	Fri 5/23/14	15 days				

ID	WBS	Task Name	Start	Finish	Duration	Dec 29, '13	Jan 5, '14	Jan 12, '14	Jan
53	6.3.2	Credo Cube R-Value Verification	Mon 5/5/14	Thu 5/22/14	14 days				
54	6.3.3	Record and insert into Final Report	Fri 5/23/14	Thu 5/29/14	5 days				
55	**7**	**Critical Design Review Preparation**	**Sun 4/20/14**	**Fri 5/9/14**	**15 days**				
56	7.1	Preparation of report	Sun 4/20/14	Thu 5/1/14	10 days				
57	7.2	CDR due to Advisor	Fri 5/2/14	Fri 5/2/14	0 days				
58	7.3	CDR Presentation with Sponsor	Fri 5/9/14	Fri 5/9/14	0 days				
	8	**Prototype Manufacturing/Testing**	**Fri 4/18/14**	**Fri 11/14/14**	**152 days**				
60	**8.1**	**Prototype Manufacturing**	**Fri 4/18/14**	**Fri 6/6/14**	**36 days**				
61	**8.1.1**	**Detailed Drawing for Manufacturing**	**Fri 4/18/14**	**Thu 4/24/14**	**5 days**				
62	8.1.1.1	Drawing of vial fixture	Fri 4/18/14	Fri 4/18/14	1 day				
63	8.1.1.2	Dimensions of VIP	Fri 4/18/14	Fri 4/18/14	1 day				
64	8.1.2	Place Part Orders (VIP, PCM)	Mon 5/12/14	Fri 5/16/14	5 days				
65	8.1.3	Receive Parts	Mon 5/19/14	Fri 6/6/14	15 days				
66	**8.2**	**Test Design**	**Mon 5/12/14**	**Thu 5/29/14**	**14 days**				
67	8.2.1	Test 1: Dimensions-10 Vials	Mon 5/12/14	Thu 5/15/14	4 days				
68	8.2.2	Test 2: Handling/Usability	Fri 5/23/14	Thu 5/29/14	5 days				
69	8.2.3	Test 3: Dimensions-Temptale	Fri 5/23/14	Thu 5/29/14	5 days				
70	8.2.4	Test 4: Drop Test	Fri 5/16/14	Thu 5/22/14	5 days				
71	8.2.5	Test 5: Heavy Load	Fri 5/16/14	Thu 5/22/14	5 days				
72	8.2.6	Test 6: ISTA 72 hr international Test Profile	Mon 5/12/14	Thu 5/15/14	4 days				
73	8.2.7	Test 7: Reliability	Fri 5/16/14	Thu 5/22/14	5 days				
74	8.2.8	Test 8: Air Shipment	Fri 5/23/14	Thu 5/29/14	5 days				
75	**8.3**	**Prototype Construction**	**Thu 9/25/14**	**Mon 10/6/14**	**8 days**				
76	8.3.1	3-D print vial fixture	Thu 9/25/14	Thu 10/2/14	6 days				
77	8.3.2	VIP Assembly (Panel toBox construction, Sealing)	Mon 9/29/14	Thu 10/2/14	4 days				
78	8.3.3	Assembly of VIP, PCM, Vials, Vial Fixture, Temperature Monitor	Mon 9/29/14	Thu 10/2/14	4 days				

	WBS	Task Name	Start	Finish	Duration	Dec 29, '13	Jan 5, '14	Jan 12, '14	Jan
79	8.3.4	Modification of Assembly instructions, insert into Final Report	Mon 9/29/14	Mon 10/6/14	6 days				
80	**8.4**	**Prototype Testing**	**Fri 10/3/14**	**Fri 11/14/14**	**32 days**				
81	8.4.1	Test 1: Dimensions-10 Vials, Tem Mon	Fri 10/3/14	Tue 10/7/14	3 days				
82	8.4.2	Test 2: Handling/Usability	Fri 10/3/14	Tue 10/7/14	3 days				
83	8.4.3	Test 3: Drop Test	Thu 11/6/14	Wed 11/12/14	5 days				
84	8.4.4	Test 4: Vehicle Stacking	Thu 11/6/14	Wed 11/12/14	5 day				
85	8.4.5	Test 5: Vibration Test	Thu 11/6/14	Wed 11/12/14	5 day				
86	8.4.6	Test 6: ISTA 48hr Domestic Test Profile	Fri 11/7/14	Mon 11/10/14	2 day				
87	8.4.7	Test 7: Reliability	Sat 11/8/14	Wed 11/12/14	4 day				
88	8.4.8	Test 8: Air Shipment	Mon 11/10/14	Fri 11/14/14	5 day				
89	9	End of Quarter Report	Fri 6/6/14	Fri 6/	's				
90	10	Update Memo to Sponsor	Fri 10/3/14	Fri 10/3/14	0 days				
91	**11**	**Final Report/Expo Compilation**	**Mon 11/3/14**	**Fri 12/5/14**	**25 days**				

ID	WBS	Task Name	Start	Finish	Duration	Dec 29, '13	Jan 5, '14	Jan 12, '14	Jan
92	11.1	Prepare for Expo	Mon 11/3/14	Wed 11/19/14	13 days				
93	11.2	Prepare Final Report	Thu 11/20/14	Fri 12/5/14	12 days				
94	11.3	Design Expo	Thu 11/20/14	Thu 11/20/14	0 days				
95	11.4	Final Project Report	Fri 12/5/14	Fri 12/5/14	0 days				

APPENDIX G: Operators' Manual

PCM Calculator

Additional Data		
Insulation Thickness (in)	Volume for PCM with Vials & Temptale (m^3)	Approx. # of beads
0.25	0.00690	3777
0.50	0.00536	2935
0.75	0.00401	2196
1.00	0.00284	1554
1.25	0.00183	1001
1.50	0.00097	532
1.75	0.00025	138
2.00	-0.00034	-186

Inputs								
Volume of VIP								
Length (in)			Height(in)			Width (in)		
9			9			8		
Payload Volume (mm^3)	Inside Temp. (C)	Outside Temp. (C)	VIP Thermal Conductivity (W/m*C)	PCM Density	PCM Latent Heat (kJ/kg)	Bead Dia. (m)	Duration (hrs)	Factor of Safety
1978300	0.00	35	0.0036	999	344	0.015	100	1.1

Data									
Insulation Thickness (in)	Insulation Thickness (m)	VIP Thermal Resistvity (m^2*C/W)	Surface Area (m^2)	Heat load (Watts)	PCM Weight (kg)	PCM Weight (lbs)	Bead PCM Required(kg)	Allowable Micro-Encapsulated PCM (kg) [Including Encapsulation Material]	Max PCM allowed w/out encapsulation (kg)
0.25	0.0064	1.76	0.290	5.76	6.03	13.26	7.63	4.41	6.89
0.50	0.0127	3.53	0.290	2.88	3.01	6.63	3.81	3.43	5.36
0.75	0.0191	5.29	0.290	1.92	2.01	4.42	2.54	2.57	4.01
1.00	0.0254	7.06	0.290	1.44	1.51	3.32	1.91	1.82	2.84
1.25	0.0318	8.82	0.290	1.15	1.21	2.65	1.53	1.17	1.83
1.50	0.0381	10.58	0.290	0.96	1.00	2.21	1.27	0.62	0.97
1.75	0.0445	12.35	0.290	0.82	0.86	1.89	1.09	0.16	0.25
2.00	0.0508	14.11	0.290	0.72	0.75	1.66	0.95	-0.22	-0.34

Figure 65: Screenshot of the PCM calculator with sample numbers

Introduction to the PCM Calculator

The Calculator shown above is able to provide the user with the correct amount of PCM from parameters entered by the user. The instructions provided below will instruct the user what parameters need to be entered and what additional information the calculator provides.

Before you begin - This calculator has been tested to be only partially accurate and requires experimental testing to identify a proper factor of safety in order to proceed with more confidence.

Parameters Required (Inputs)

Additional Data

Insulation Thickness (in)	Volume for PCM with Vials & Temptale (m^3)	Approx. # of beads
0.25	0.00690	3777
0.50	0.00536	2935
0.75	0.00401	2196
1.00	0.00284	1554
1.25	0.00183	1001
1.50	0.00097	532
1.75	0.00025	138
2.00	-0.00034	-186

Inputs

Volume of VIP

Length (in)	Height(in)	Width (in)
9	9	8

Payload Volume (mm^3)	Inside Temp. (C)	Outside Temp. (C)	VIP Thermal Conductivity (W/m*C)	PCM Density	PCM Latent Heat (kJ/kg)	Bead Dia. (m)	Duration (hrs)	Factor of Safety
1978300	0.00	35	0.0036	999	344	0.015	100	1.1

Data

Insulation Thickness (in)	Insulation Thickness (m)	VIP Thermal Resistvity (m^2*C/W)	Surface Area (m^2)	Heat load (Watts)	PCM Weight (kg)	PCM Weight (lbs)	Bead PCM Required(kg)	Allowable Micro-Encapsulated PCM (kg) [Including Encapsulation Material]	Max PCM allowed w/out encapsulation (kg)
0.25	0.0064	1.76	0.290	5.76	6.03	13.26	7.63	4.41	6.89
0.50	0.0127	3.53	0.290	2.88	3.01	6.63	3.81	3.43	5.36
0.75	0.0191	5.29	0.290	1.92	2.01	4.42	2.54	2.57	4.01
1.00	0.0254	7.06	0.290	1.44	1.51	3.32	1.91	1.82	2.84
1.25	0.0318	8.82	0.290	1.15	1.21	2.65	1.53	1.17	1.83
1.50	0.0381	10.58	0.290	0.96	1.00	2.21	1.27	0.62	0.97
1.75	0.0445	12.35	0.290	0.82	0.86	1.89	1.09	0.16	0.25
2.00	0.0508	14.11	0.290	0.72	0.75	1.66	0.95	-0.22	-0.34

Figure 66: User inputs highlighted with a Bright red box

Under the 'Inputs' tab are three white boxes which are the outer dimensions of the VIP (length, height, & width). This portion should be adjusted accordingly. Later on, if the box is not voluptuous enough to contain a sufficient amount of PCM, these dimensions may need to increase.

Under the second row of Inputs, the calculator requires the user to enter parameters for the payload, VIP, and PCM. Going from left to right, the description of the columns are as follows:

- The payload volume consist of the vials and temperature monitor.
- The inside temperature of the container will be determined by the melting point of the PCM used. In the calculator pictured above, water was the PCM, thus 0C was the inside temperature.
- The outside temperature can be any temperature. For the example above, 35C was used because it is used as a slight fudge factor since it is never always 35C.
- VIP Thermal Conductivity is always provided by the manufacturer. Double check for units on the Thermal Conductivity from the manufacturer (for this calculator, units shall be in W/m*C).
- The density of the PCM is provided by the manufacturer.
- Bead diameter can be provided by the manufacturer or measured out manually.
- The duration is how long the user wants to maintain the inside temperature before any excursions.
- The last column on the right under the inputs tab requires a factor of safety which must be calculated for experimentally. This factor of safety is analogous to a 'fudge factor.'

Data Calculated

Additional Data		
Insulation Thickness (in)	Volume for PCM with Vials & Temptale (m^3)	Approx. # of beads
0.25	0.00690	3777
0.50	0.00536	2935
0.75	0.00401	2196
1.00	0.00284	1554
1.25	0.00183	1001
1.50	0.00097	532
1.75	0.00025	138
2.00	-0.00034	-186

Inputs								
Volume of VIP								
Length (in)			Height(in)			Width (in)		
9			9			8		
Payload Volume (mm^3)	Inside Temp. (C)	Outside Temp. (C)	VIP Thermal Conductivity (W/m*C)	PCM Density	PCM Latent Heat (kJ/kg)	Bead Dia. (m)	Duration (hrs)	Factor of Safety
1978300	0.00	35	0.0036	999	344	0.015	100	1.1

Data									
Insulation Thickness (in)	Insulation Thickness (m)	VIP Thermal Resistvity (m^2*C/W)	Surface Area (m^2)	Heat load (Watts)	PCM Weight (kg)	PCM Weight (lbs)	Bead PCM Required(kg)	Allowable Micro-Encapsulated PCM (kg) [Including Encapsulation Material]	Max PCM allowed w/out encapsulation (kg)
0.25	0.0064	1.76	0.290	5.76	6.03	13.26	7.63	4.41	6.89
0.50	0.0127	3.53	0.290	2.88	3.01	6.63	3.81	3.43	5.36
0.75	0.0191	5.29	0.290	1.92	2.01	4.42	2.54	2.57	4.01
1.00	0.0254	7.06	0.290	1.44	1.51	3.32	1.91	1.82	2.84
1.25	0.0318	8.82	0.290	1.15	1.21	2.65	1.53	1.17	1.83
1.50	0.0381	10.58	0.290	0.96	1.00	2.21	1.27	0.62	0.97
1.75	0.0445	12.35	0.290	0.82	0.86	1.89	1.09	0.16	0.25
2.00	0.0508	14.11	0.290	0.72	0.75	1.66	0.95	-0.22	-0.34

Figure 67: Data output boxed in bright red

This next large portion boxed in bright red is where most of the output data is located. Each column in this section will be explained from left to right as follows:

- The first column on the left is the insulation thickness in inches from 0.25 - 2.00 inches.
- The second column is the insulation thickness converted to meters since insulation thickness is more commonly spoken of in English units. While calculations are more practical in Metric.
- The third column is the thermal resistivity of the VIP. This is just the insulation thickness divided by the thermal conductivity.
- The fourth column is the external surface area of the VIP.
- The fifth column is the heat load in Watts coming into the package.
- The sixth and seventh column show the amount of weight in kg and lbs of PCM respectively. This amount of PCM is enough to satisfy the duration of time entered. Although this weight is of PCM with no encapsulation.
- The eighth column provides the user with the weight in kg of encapsulated PCM required to last for the duration the user has set. In this example, with one inch thick VIP, 1.73 kg of encapsulated PCM would satisfy the system at 0C for 100 hours; according to the calculator. According to PureTemp, the encapsulation partakes approximately 15% of the total weight, thus we multiplied column seven by 15% in order to obtain this column's data.

- The ninth and one of the most important columns in this calculator is the amount in kg of encapsulated PCM that will fit inside this container. This amount will also maintain the inside temperature for the duration the user has set. This column is color coded, green means all parameters will be satisfied, while red means not all parameters will be satisfied.
  Reminder- When numbers are negative in this column, it signifies that the internal volume is insufficient in size to satisfy all requirements.
- The tenth and final column shows the amount of PCM that will fit inside the package without the encapsulation.

Additional Data

Additional Data		
Insulation Thickness (in)	Volume for PCM with Vials & Temptale (m^3)	Approx. # of beads
0.25	0.00690	3777
0.50	0.00536	2935
0.75	0.00401	2196
1.00	0.00284	1554
1.25	0.00183	1001
1.50	0.00097	532
1.75	0.00025	138
2.00	-0.00034	-186

Inputs								
Volume of VIP								
Length (in)			Height(in)			Width (in)		
9			9			8		
Payload Volume (mm^3)	Inside Temp. (C)	Outside Temp. (C)	VIP Thermal Conductivity (W/m*C)	PCM Density	PCM Latent Heat (kJ/kg)	Bead Dia. (m)	Duration (hrs)	Factor of Safety
1978300	0.00	35	0.0036	999	344	0.015	100	1.1

Data									
Insulation Thickness (in)	Insulation Thickness (m)	VIP Thermal Resistvity (m^2*C/W)	Surface Area (m^2)	Heat load (Watts)	PCM Weight (kg)	PCM Weight (lbs)	Bead PCM Required(kg)	Allowable Micro-Encapsulated PCM (kg) [Including Encapsulation Material]	Max PCM allowed w/out encapsulation (kg)
0.25	0.0064	1.76	0.290	5.76	6.03	13.26	7.63	4.41	6.89
0.50	0.0127	3.53	0.290	2.88	3.01	6.63	3.81	3.43	5.36
0.75	0.0191	5.29	0.290	1.92	2.01	4.42	2.54	2.57	4.01
1.00	0.0254	7.06	0.290	1.44	1.51	3.32	1.91	1.82	2.84
1.25	0.0318	8.82	0.290	1.15	1.21	2.65	1.53	1.17	1.83
1.50	0.0381	10.58	0.290	0.96	1.00	2.21	1.27	0.62	0.97
1.75	0.0445	12.35	0.290	0.82	0.86	1.89	1.09	0.16	0.25
2.00	0.0508	14.11	0.290	0.72	0.75	1.66	0.95	-0.22	-0.34

Figure 68: Additional data output boxed in bright red

The last small portion of additional data is extra information. The description of these last few columns are as follows:

- The first column on the left of the additional data section is the insulation thickness from 0.25 - 2.00 inches.
- The second column shows the amount of volume left in the payload area for PCM after subtracting away the volume of the vials and temperature monitor.
- The third and final column is the approximate number of beads that can physically fit inside the container.

Assembling the Mac-kage with VIP

For assembly instructions, see manufacturing section…..

MAC-KAGE Pack-out Instructions

The following instructions are to be used when chilled pharmaceutical and biologics need to be shipped in a safe and inexpensive manner. Prior to shipping, follow these instructions to prepare the package to be shipped.

Have an assembled MAC-kage ready

Follow assembly instructions in sections ____ to obtain a fully assembled MAC-kage. The package should look like the figure below. Afterwards, proceed to the next step to continue pack-out instructions.

Figure 69: Assembled MAC-kage with VIP's (Lid missing from picture)

Prepare MAC-kage for PCM & payload

Line the inside of the package with a plastic bag in order to prevent beads from spilling everywhere when opening the package at a later day.

Figure 70: MAC-kage lined with a plastic bag

Fill the MAC-kage

The next step is to obtain the vials from refrigeration and have a temperature monitor programmed and ready to go. Fill the package with the proper amount of PCM according to the PCM calculator.

Figure 71: Filling the MAC-kage with the proper amount of PCM according to the PCM calculator

Once the proper amount of PCM is packed, place vials and temperature monitor inside. When everything is in the bag, close up the bag and place the last VIP in the cardboard box. Reminder - Turn on the temperature monitor prior to placing it inside the package.

Figure 72: MAC-kage filled with PCM, vials, and a temperature monitor ready to be shipped.

Figure 73: MAC-kage packed and sealed with the last VIP

Close up the MAC-kage and Ship it

The last step is to tape the package and place shipping labels. Reminder - only use clear packaging tape, other types of tape are not as durable and are not made for shipping purposes. Afterwards, the package should look similar to the figure below. It also would not hurt to tape the edges and corners with extra tape.

Figure 74: MAC-kage Packed, Sealed, and Taped all Ready to be shipped out for Clinical Trials.

APPENDIX G: Operators' Manual

PCM Calculator

Additional Data		
Insulation Thickness	Volume for PCM with Vials & Temptale (m^3)	Approx. # of beads
0.25	0.00690	3777
0.50	0.00536	2935
0.75	0.00401	2196
1.00	0.00284	1554
1.25	0.00183	1001
1.50	0.00097	532
1.75	0.00025	138
2.00	-0.00034	-186

Inputs									
Volume of VIP									
Length (in)			Height(in)			Width (in)			
9			9			8			
Payload Volume (mm^3)	Inside Temp. (C)	Outside Temp. (C)	VIP Thermal Conductivity (W/m*C)	PCM Density	PCM Latent Heat (kJ/kg)	Bead Dia. (m)	Duration (hrs)	Factor of Safety	Encapsulation Factor
1978300	0.00	35	0.0036	999	344	0.015	100	1.1	1.15

Data									
Insulation Thickness (in)	Insulation Thickness (m)	VIP Thermal Resistvity (m^2*C/W)	Surface Area (m^2)	Heat load (Watts)	PCM Weight (kg)	PCM Weight (lbs)	Bead PCM Required(kg)	Allowable Micro-Encapsulated PCM (kg) [Including Encapsulation Material]	Max PCM allowed w/out encapsulation (kg)
0.25	0.0064	1.76	0.290	5.76	6.03	13.26	7.63	4.41	6.89
0.50	0.0127	3.53	0.290	2.88	3.01	6.63	3.81	3.43	5.36
0.75	0.0191	5.29	0.290	1.92	2.01	4.42	2.54	2.57	4.01
1.00	0.0254	7.06	0.290	1.44	1.51	3.32	1.91	1.82	2.84
1.25	0.0318	8.82	0.290	1.15	1.21	2.65	1.53	1.17	1.83
1.50	0.0381	10.58	0.290	0.96	1.00	2.21	1.27	0.62	0.97
1.75	0.0445	12.35	0.290	0.82	0.86	1.89	1.09	0.16	0.25
2.00	0.0508	14.11	0.290	0.72	0.75	1.66	0.95	-0.22	-0.34

Figure 75: Screen Shot of the PCM Calculator with Sample Numbers

Introduction to the PCM Calculator

The Calculator shown above is able to provide the user with the correct amount of PCM from parameters entered by the user. The directions provided below will instruct the user what parameters need to be entered and what additional information the calculator provides.

Before you begin - This calculator has been tested to be only partially accurate and requires experimental testing to identify a proper factor of safety in order to proceed with more confidence.

Parameters Required (Inputs)

Additional Data		
Insulation Thickness	Volume for PCM with Vials & Temptale (m^3)	Approx. # of beads
0.25	0.00690	3777
0.50	0.00536	2935
0.75	0.00401	2196
1.00	0.00284	1554
1.25	0.00183	1001
1.50	0.00097	532
1.75	0.00025	138
2.00	-0.00034	-186

Inputs									
Volume of VIP									
Length (in)			Height(in)			Width (in)			
9			9			8			
Payload Volume (mm^3)	Inside Temp. (C)	Outside Temp. (C)	VIP Thermal Conductivity (W/m*C)	PCM Density	PCM Latent Heat (kJ/kg)	Bead Dia. (m)	Duration (hrs)	Factor of Safety	Encapsulation Factor
1978300	0.00	35	0.0036	999	344	0.015	100	1.1	1.15

Data									
Insulation Thickness (in)	Insulation Thickness (m)	VIP Thermal Resistvity (m^2*C/W)	Surface Area (m^2)	Heat load (Watts)	PCM Weight (kg)	PCM Weight (lbs)	Bead PCM Required(kg)	Allowable Micro-Encapsulated PCM (kg) [Including Encapsulation Material]	Max PCM allowed w/out encapsulation (kg)
0.25	0.0064	1.76	0.290	5.76	6.03	13.26	7.63	4.41	6.89
0.50	0.0127	3.53	0.290	2.88	3.01	6.63	3.81	3.43	5.36
0.75	0.0191	5.29	0.290	1.92	2.01	4.42	2.54	2.57	4.01
1.00	0.0254	7.06	0.290	1.44	1.51	3.32	1.91	1.82	2.84
1.25	0.0318	8.82	0.290	1.15	1.21	2.65	1.53	1.17	1.83
1.50	0.0381	10.58	0.290	0.96	1.00	2.21	1.27	0.62	0.97
1.75	0.0445	12.35	0.290	0.82	0.86	1.89	1.09	0.16	0.25
2.00	0.0508	14.11	0.290	0.72	0.75	1.66	0.95	-0.22	-0.34

Figure 76: User Inputs Highlighted with a Bright Red Box

Under the ‘Inputs’ tab are three white boxes which are the outer dimensions of the VIP (length, height, & width). This portion should be adjusted accordingly. Later on, if the box is not large enough to contain a sufficient amount of PCM, these dimensions may need to increase.

Under the second row of Inputs, the calculator requires the user to enter parameters for the payload, VIP, and PCM. Going from left to right, the description of the columns are as follows:

- The payload volume consist of the vials and temperature monitor.
- The inside temperature of the container will be determined by the melting point of the PCM used. In the calculator pictured above, water was the PCM, thus 0C was the inside temperature.
- The outside temperature can be any temperature. For the example above, 35C was used because it is used as a slight fudge factor since it is never always 35C.
- VIP Thermal Conductivity is always provided by the manufacturer. Double check for units on the Thermal Conductivity from the manufacturer (for this calculator, units shall be in W/m*C).
- The density of the PCM is provided by the manufacturer.
- Bead diameter can be provided by the manufacturer or measured out manually.
- The duration is how long the user wants to maintain the inside temperature before any excursions.
- A factor of safety must be calculated for experimentally in order to increase accuracy of this calculator. This factor of safety is analogous to a ‘fudge factor.’
- The last column on the right under the inputs tab requires a Encapsulation factor. This factor takes into account the weight of the PCM in addition to the

encapsulation. For instance, PureTemp has a weight increase of approximately 10-15% due to the micro-encapsulation.

Data Calculated

Additional Data		
Insulation Thickness	Volume for PCM with Vials & Temptale (m^3)	Approx. # of beads
0.25	0.00690	3777
0.50	0.00536	2935
0.75	0.00401	2196
1.00	0.00284	1554
1.25	0.00183	1001
1.50	0.00097	532
1.75	0.00025	138
2.00	-0.00034	-186

Inputs									
Volume of VIP									
Length (in)			Height(in)			Width (in)			
9			9			8			
Payload Volume (mm^3)	Inside Temp. (C)	Outside Temp. (C)	VIP Thermal Conductivity (W/m*C)	PCM Density	PCM Latent Heat (kJ/kg)	Bead Dia. (m)	Duration (hrs)	Factor of Safety	Encapsulation Factor
1978300	0.00	35	0.0036	999	344	0.015	100	1.1	1.15

Data									
Insulation Thickness (in)	Insulation Thickness (m)	VIP Thermal Resistvity (m^2*C/W)	Surface Area (m^2)	Heat load (Watts)	PCM Weight (kg)	PCM Weight (lbs)	Bead PCM Required(kg)	Allowable Micro-Encapsulated PCM (kg) [Including Encapsulation Material]	Max PCM allowed w/out encapsulation (kg)
0.25	0.0064	1.76	0.290	5.76	6.03	13.26	7.63	4.41	6.89
0.50	0.0127	3.53	0.290	2.88	3.01	6.63	3.81	3.43	5.36
0.75	0.0191	5.29	0.290	1.92	2.01	4.42	2.54	2.57	4.01
1.00	0.0254	7.06	0.290	1.44	1.51	3.32	1.91	1.82	2.84
1.25	0.0318	8.82	0.290	1.15	1.21	2.65	1.53	1.17	1.83
1.50	0.0381	10.58	0.290	0.96	1.00	2.21	1.27	0.62	0.97
1.75	0.0445	12.35	0.290	0.82	0.86	1.89	1.09	0.16	0.25
2.00	0.0508	14.11	0.290	0.72	0.75	1.66	0.95	-0.22	-0.34

Figure 77: Data Output Boxed in Bright Red

This next large portion boxed in bright red is where most of the output data is located. Each column in this section will be explained from left to right as follows:

- The first column on the left is the insulation thickness in inches from 0.25 - 2.00 inches.
- The second column is the insulation thickness converted to meters since insulation thickness is more commonly spoken of in English units. While calculations are more practical in Metric.
- The third column is the thermal resistivity of the VIP. This is just the insulation thickness divided by the thermal conductivity.
- The fourth column is the external surface area of the VIP.
- The fifth column is the heat load in Watts coming into the package.
- The sixth and seventh column show the amount of weight in kg and lbs of PCM respectively. This amount of PCM is enough to satisfy the duration of time entered. Although this weight is of PCM with no encapsulation.
- The eighth column provides the user with the weight in kg of encapsulated PCM required to last for the duration the user has set. In this example, with one inch thick VIP, 1.73 kg of encapsulated PCM would satisfy the system at 0C for 100 hours. According to PureTemp, the encapsulation partakes approximately 15% of the total weight, thus we multiplied column seven by 15% in order to obtain this column's data.

- The ninth and one of the most important columns in this calculator is the amount in kg of encapsulated PCM that will fit inside this container. This amount will also maintain the inside temperature for the duration the user has set. This column is color coded; green means all parameters will be satisfied, while red means not all parameters will be satisfied.
  Note- When numbers are negative in this column, it signifies that the internal volume is insufficient in size to satisfy all requirements.
- The tenth and final column shows the amount of PCM that will fit inside the package without the encapsulation.

Additional Data

Additional Data		
Insulation Thickness	Volume for PCM with Vials & Temptale (m^3)	Approx. # of beads
0.25	0.00690	3777
0.50	0.00536	2935
0.75	0.00401	2196
1.00	0.00284	1554
1.25	0.00183	1001
1.50	0.00097	532
1.75	0.00025	138
2.00	-0.00034	-186

Inputs									
Volume of VIP									
Length (in)			Height(in)			Width (in)			
9			9			8			
Payload Volume (mm^3)	Inside Temp. (C)	Outside Temp. (C)	VIP Thermal Conductivity (W/m*C)	PCM Density	PCM Latent Heat (kJ/kg)	Bead Dia. (m)	Duration (hrs)	Factor of Safety	Encapsulation Factor
1978300	0.00	35	0.0036	999	344	0.015	100	1.1	1.15

Data									
Insulation Thickness (in)	Insulation Thickness (m)	VIP Thermal Resistvity (m^2*C/W)	Surface Area (m^2)	Heat load (Watts)	PCM Weight (kg)	PCM Weight (lbs)	Bead PCM Required(kg)	Allowable Micro-Encapsulated PCM (kg) [Including Encapsulation Material]	Max PCM allowed w/out encapsulation (kg)
0.25	0.0064	1.76	0.290	5.76	6.03	13.26	7.63	4.41	6.89
0.50	0.0127	3.53	0.290	2.88	3.01	6.63	3.81	3.43	5.36
0.75	0.0191	5.29	0.290	1.92	2.01	4.42	2.54	2.57	4.01
1.00	0.0254	7.06	0.290	1.44	1.51	3.32	1.91	1.82	2.84
1.25	0.0318	8.82	0.290	1.15	1.21	2.65	1.53	1.17	1.83
1.50	0.0381	10.58	0.290	0.96	1.00	2.21	1.27	0.62	0.97
1.75	0.0445	12.35	0.290	0.82	0.86	1.89	1.09	0.16	0.25
2.00	0.0508	14.11	0.290	0.72	0.75	1.66	0.95	-0.22	-0.34

Figure 78: Additional Data Output Boxed in Bright Red

The last small portion of additional data is extra information. The description of these last few columns are as follows:

- The first column on the left of the additional data section is the insulation thickness from 0.25 - 2.00 inches.
- The second column shows the amount of volume left in the payload area for PCM after subtracting away the volume of the vials and temperature monitor.
- The third and final column is the approximate number of beads that can physically fit inside the container.

Assembling the Mac-kage with VIP

For assembly instructions, see manufacturing section 5.2.

MAC-KAGE Pack-out Instructions

The following instructions are to be used when chilled pharmaceutical and biologics need to be shipped in a safe and inexpensive manner. Prior to shipping, follow these instructions to prepare the package to be shipped.

Have an assembled MAC-kage ready

Follow assembly instructions in sections 5.2 to obtain a fully assembled MAC-kage. The package should look like the figure below. Afterwards, proceed to the next step to continue pack-out instructions.

Figure 79: Assembled MAC-kage with VIP's (Lid missing from picture)

Prepare MAC-kage for PCM & payload

Line the inside of the package with a plastic bag in order to prevent beads from spilling everywhere when opening the package at a later day.

Figure 80: MAC-kage Lined with a Plastic Bag

Fill the MAC-kage

The next step is to obtain the vials from refrigeration and have a temperature monitor programmed and ready to go. Fill the package with the proper amount of PCM according to the PCM calculator.

Figure 81: Filling the MAC-kage with the Proper Amount of PCM According to the PCM Calculator

Once the proper amount of PCM is packed, place vials and temperature monitor inside. When everything is in the bag, close up the bag and place the last VIP in the cardboard box. Reminder - Turn on the temperature monitor prior to placing it inside the package.

Figure 82: MAC-kage Filled with PCM, Vials, and a Temperature Monitor Ready to be shipped.

Figure 83: MAC-kage Packed and Sealed with the Last VIP

Close up the MAC-kage and Ship it

The last step is to tape the package and place shipping labels.
Note- only use clear packaging tape, other types of tape are not as durable and are not made for shipping purposes. Afterwards, the package should look similar to the figure below. It also would not hurt to tape the edges and corners with extra tape.

Figure 84: MAC-kage Packed, Sealed, and Taped all Ready to be shipped out for Clinical Trials.

APPENDIX H: Design Verification Plan and Report

DVP&R													
Report Date:		**Assembly:** Temperature Controlled Packaging Unit for Pharmeacutical				**Sponsor:** Clinical Supplies Management					**REPORTING ENGINEER:** Melinda Phan		
TEST PLAN										**TEST REPORT**			
Item No	**Specification or Clause Reference**	**Test Description**	**Acceptance Criteria**	**Test Responsibility**	**Test Stage**	**SAMPLES TESTED**		**TIMING**		**TEST RESULTS**			**NOTES**
						Quantity	**Type**	**Start date**	**Finish date**	**Test Result**	**Quantity Pass**	**Quantity Fail**	
1	Appropriate Dimensions	Prototype can hold all requirements	By Inspection, Container has space for 1 TempTale or 1 EI Pro temperature monitor, 10 20mL vials and the required amount of PCM	Abe	DV	1	D	10/20/2014	10/24/2014	PASS	1	0	
2	Handleability	Time an operator opening a Credo Cube and time opening a MAC container	Container can be opened in the same time or less than the Credo Cube	Abe	DV	1	D	10/27/2014	10/31/2014	PASS	1	0	
3	Temperature Test for Transport Packaging (ISTA)	Follow the summer profile in ISTA prototcol to apply heat load on MAC containers	Internal temperature maintains 0+/- 3C >= 96 hours	Yufay	DV	5	D	11/7/2014	11/11/2014	FAIL	0	5	
4	FedEx Testing Protocol	FedEx Free-Fall Drop Test, Compression Test, Rotary	0 Vials cracked after 10 foot drops (5)	Melinda	DV	3	D	11/6/2014	11/14/2014	PASS	3	0	
5	Actual Environment	Shipped in 2x overnight FedEx shipments	No deviating from temperature, no vials breaking	Melinda	DV	1	D	11/12/2014	11/14/2014	PASS	1	0	

Figure 85: DVPR

APPENDIX I: Raw Data and Vendor Testing Results

CalPoly

ALARM

Additional Information

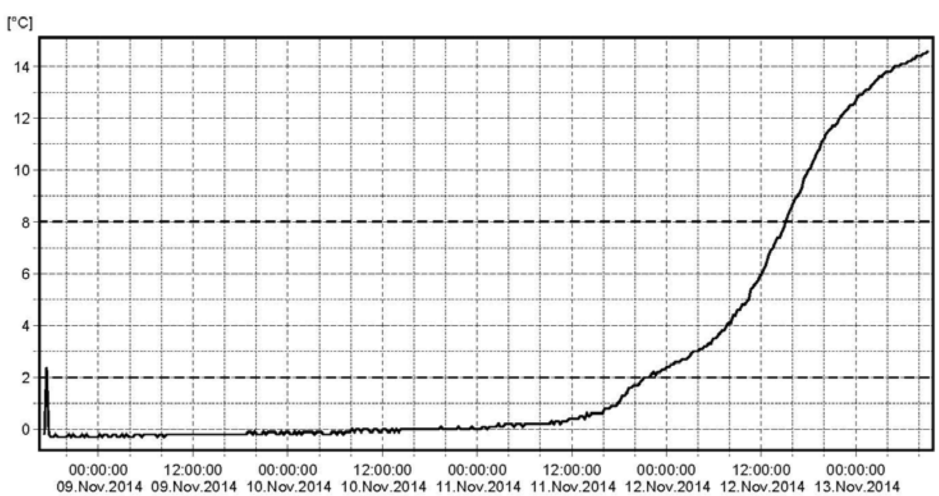
Device Configuration

Type:	Libero Ti1 V1.36	Inspection Range:	Last Transit to Arrived
Logger ID:	10225589	Current State:	Logging Arrived
Log Interval / Duration:	15 m / 166.7 d	Remaining Battery:	347 d
Log Mode:	Start/Stop	Logger Start:	08.Nov.2014 17:02:09
Report Time Base:	GMT	Checksum:	P000 / 2.714.280.121
Configured by:	C1361, YUFAY-PC/Yufay, 08.Nov.2014 16:12:25		

Alarm Conditions		Total Time		Status
Upper Threshold:	8.0 °C	Time above Threshold:	18.0 h	ALARM
Lower Threshold:	2.0 °C	Time below Threshold:	3.2 d	ALARM
Alarm Delay:	0 s			

Logging Results

Highest Temperature:	14.6 °C; 13.Nov.2014 09:02:09	Transit Start at:	08.Nov.2014 17:02:09
Lowest Temperature:	-0.3 °C; 08.Nov.2014 18:02:09	Arrived at:	13.Nov.2014 09:07:14
Average Temperature:	2.7 °C	Alarm at:	08.Nov.2014 17:17:09
MKT	4.3 °C	File created:	13.Nov.2014 09:13:19



CalPoly

ALARM

Additional Information

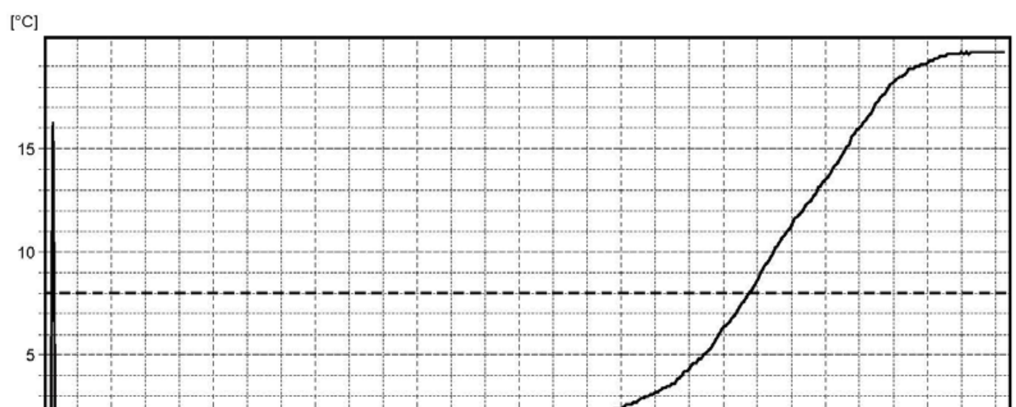
Device Configuration

Type:	Libero Ti1 V1.36	Inspection Range:	Last Transit to Arrived
Logger ID:	10225609	Current State:	Logging Arrived
Log Interval / Duration:	15 m / 166.7 d	Remaining Battery:	381 d
Log Mode:	Start/Stop	Logger Start:	08.Nov.2014 16:43:49
Report Time Base:	GMT	Checksum:	P000 / 898.131.376
Configured by:	C1361, YUFAY-PC/Yufay, 08.Nov.2014 16:12:03		

Alarm Conditions		Total Time		Status
Upper Threshold:	8.0 °C	Time above Threshold:	30.3 h	ALARM
Lower Threshold:	2.0 °C	Time below Threshold:	58.0 h	ALARM
Alarm Delay:	0 s			

Logging Results

Highest Temperature:	19.7 °C; 13.Nov.2014 03:43:49	Transit Start at:	08.Nov.2014 16:43:49
Lowest Temperature:	-0.5 °C; 08.Nov.2014 17:58:49	Arrived at:	13.Nov.2014 09:07:52
Average Temperature:	5.4 °C	Alarm at:	08.Nov.2014 16:43:49
MKT	8.8 °C	File created:	13.Nov.2014 09:11:52



CalPoly

ALARM

Additional Information

Device Configuration

Type:	Libero Ti1 V1.36	Inspection Range:	Last Transit to Arrived
Logger ID:	10225578	Current State:	Logging Arrived
Log Interval / Duration:	15 m / 166.7 d	Remaining Battery:	361 d
Log Mode:	Start/Stop	Logger Start:	08.Nov.2014 17:05:15
Report Time Base:	GMT	Checksum:	P000 / 2.714.280.121
Configured by:	C1361, YUFAY-PC/Yufay, 08.Nov.2014 16:12:48		

Alarm Conditions		Total Time		Status
Upper Threshold:	8.0 °C	Time above Threshold:	4.4 d	ALARM
Lower Threshold:	2.0 °C	Time below Threshold:	0 s	OK
Alarm Delay:	0 s			

Logging Results

Highest Temperature:	36.7 °C; 12.Nov.2014 14:20:15	Transit Start at:	08.Nov.2014 17:05:15
Lowest Temperature:	18.4 °C; 08.Nov.2014 17:05:15	Arrived at:	13.Nov.2014 02:43:44
Average Temperature:	31.2 °C	Alarm at:	08.Nov.2014 17:05:15
MKT	31.8 °C	File created:	13.Nov.2014 09:17:03

CalPoly3

ALARM

Additional Information

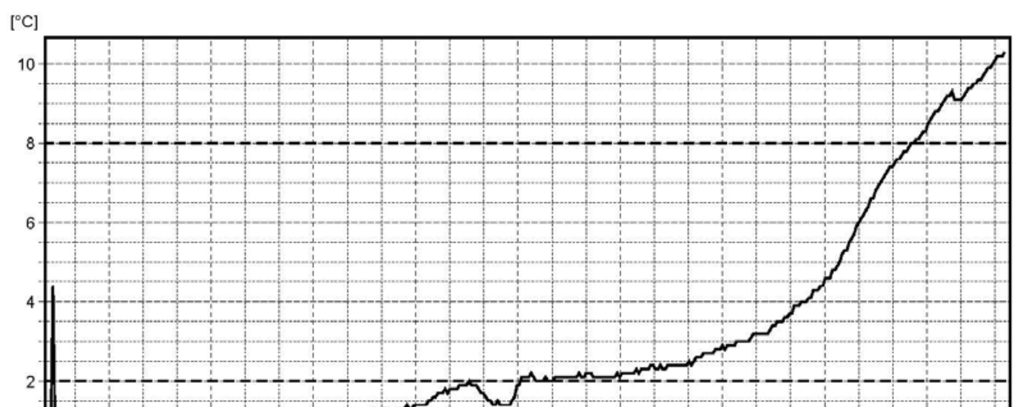
Device Configuration

Type:	Libero Ti1 V1.36	Inspection Range:	Last Transit to Arrived
Logger ID:	10228441	Current State:	Logging Arrived
Log Interval / Duration:	15 m / 166.7 d	Remaining Battery:	331 d
Log Mode:	Start/Stop	Logger Start:	08.Nov.2014 17:00:47
Report Time Base:	GMT	Checksum:	P000 / 1.490.106.555
Configured by:	C1361, YUFAY-PC/Yufay, 08.Nov.2014 16:11:17		

Alarm Conditions		Total Time		Status
Upper Threshold:	8.0 °C	Time above Threshold:	10.5 h	ALARM
Lower Threshold:	2.0 °C	Time below Threshold:	55.0 h	ALARM
Alarm Delay:	0 s			

Logging Results

Highest Temperature:	10.3 °C; 13.Nov.2014 09:00:47	Transit Start at:	08.Nov.2014 17:00:47
Lowest Temperature:	-0.2 °C; 08.Nov.2014 18:45:47	Arrived at:	13.Nov.2014 09:08:35
Average Temperature:	2.8 °C	Alarm at:	08.Nov.2014 17:15:47
MKT	3.3 °C	File created:	13.Nov.2014 09:09:29



CalPoly

ALARM

Additional Information

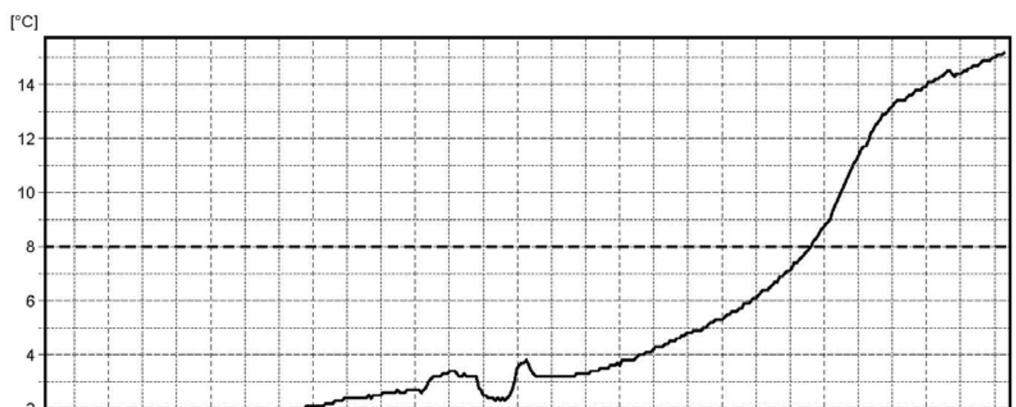
Device Configuration

Type:	Libero Ti1 V1.36	Inspection Range:	Last Transit to Arrived
Logger ID:	10225605	Current State:	Logging Arrived
Log Interval / Duration:	15 m / 166.7 d	Remaining Battery:	331 d
Log Mode:	Start/Stop	Logger Start:	08.Nov.2014 17:04:31
Report Time Base:	GMT	Checksum:	P000 / 2.714.280.121
Configured by:	C1361, YUFAY-PC/Yufay, 08.Nov.2014 16:13:10		

Alarm Conditions		Total Time		Status
Upper Threshold:	8.0 °C	Time above Threshold:	22.8 h	ALARM
Lower Threshold:	2.0 °C	Time below Threshold:	29.3 h	ALARM
Alarm Delay:	0 s			

Logging Results

Highest Temperature:	15.2 °C; 13.Nov.2014 09:04:31	Transit Start at:	08.Nov.2014 17:04:31
Lowest Temperature:	-0.2 °C; 08.Nov.2014 17:49:31	Arrived at:	13.Nov.2014 09:05:37
Average Temperature:	4.7 °C	Alarm at:	08.Nov.2014 17:19:31
MKT	6.2 °C	File created:	13.Nov.2014 09:15:27



Service Information

PDD Contact : John Purinton **Test or Evaluation :** Test **Report Number :** 55099

Received Date : 11/11/2014 **Processed Date :** 11/18/2014 **Express**

Customer Information

Acct # : 212752797
CLINICAL SUPPLIES MANAGEMENT
342 42ND ST S
FARGO, ND 58103 USA

Contact: MELINDA PHAN

Phone: 714716961

FedEx Location Information

Express Station ID: FARA

Ground Terminal Id: FARG

Sales Professional : Jean M. Broad

Phone Number : 701-799-0087

Field Engineer: Michelle Duda

Phone Number : 651-337-1898

Product Information

Commodity Code : 24 **UN No :** 1845 **Model Number:** 1 **Pcs. Per Pkg:** 10

Values : 45.00 **Product Description:** MAC -

Packaging Information

Size : L (in): 9.5 **W (in):** 9.5 **H(in):** 8 **Wt (lb):** 6 **Outer Container Type:** Corrugated

Container Specs: C-Flute Singlewall 200 Burst Test

Other Outer Info: RSC style

Inner Packaging I: Kevothermal Vacuum Insulation Panels **Inner Packaging II:** glass vials **Sealing Method:** PST on top middle seam, duct tape on bottom middle seam

Other Inner Info: Kevothermal Vacuum Insulation Panels, untied plastic bag, 10-glass vials with screw caps with plastic die cut, coolant was water absorbent bead, temperature sensor in zip lock bag.

Test Procedures Completed

Test Type : Domestic - FedEx

Drop Height (in) : 30 inches **Drop Sequence :** One Set Free - Fall

Drop Results: Package Failed - See "Comments" section on page 2

Compression Factor: 5 **Compression Load (lbf) :** 316

Compression Results: Meets Minimum Specifications

Vibration Profile: Domestic FedEx **Vibration Duration:** 60 Minutes Rotary

Vibration Results: Package Failed

Test Results

Result:	Failed

Definitions of Results

Passed:	A package, with article, that has passed all the Fedex Standard Testing Procedures. For commodities restricted under Liabilities Not Assumed in the Fedex Service Guide, Service Guide Terms and Conditions will take precedence.
Failed:	A package, with article, that has failed all FedEx Standard Testing Procedures.
Pending:	A package, with article, that has been tested to all FedEx Standard Test Procedures. Confirmation of results is subject to customer inspection.

Comments and Packaging Recommendations*

Prototype Packaging. FedEx Package Testing Procedures for shipment under 150 lbs., or ISTA 6-FedEx-A, were followed for this test.

Initially the test package failed due to the use of duct tape for tape sealing closure. Some of the glass vials came loose from the plastic containment holder. Also some of the screw caps were loose on the glass vials. Poly bag was not tied.

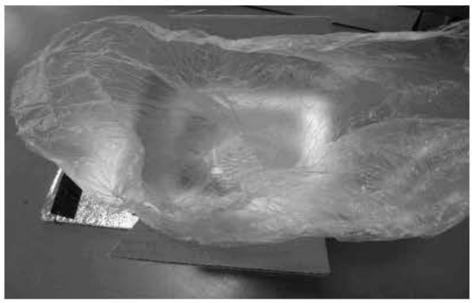
Liabilities Not Assumed, Section DD. Damages indicated by any shockwatch, tiltmeter or temperature instruments. (Reference 2014 FedEx Service Guide)

Customers are responsible for determining what packaging is required before shipping clinical. If you have questions about clinical packaging requirements, please contact your local lab or call the FedEx DG Hotline: 800-463-3339 (silent prompt 81).

Sealing your package: **Do not use** cellophane tape, **duct tape**, masking tape, string, or rope to seal packages. Also reference the FedEx Service Guide 2014.
Reference FedEx General Packaging Guidelines: http://www.fedex.com/us/services/pdf/packaging/GrlPkgGuidelines_fxcom.pdf

Photos / Drawings (if Applicable)









J3894-ITEM1
9x9x1VIP-2
MfgDate: 10/14/14
SHIFTA
KEVOTHERMAL

* Our provision of advice, assistance or guidance on the appropriate packaging of shipment does not constitute acceptance of liability, unless such advice, assistance or guidance is in writing from the FedEx Packaging Design and Development department and expressly accepts liability in the event of a damaged shipment.

FedEx Packaging Design and Development 789 Progress Rd, Collierville, TN 38017
Toll Free 800.633.7019 option 5 Fax : 901.492.7278

Service Information

PDD Contact : John Purinton **Test or Evaluation :** Test **Report Number :** 55100

Received Date : 11/11/2014 **Processed Date :** 11/18/2014 **Express**

Customer Information

Acct # : 212752797
CLINICAL SUPPLIES MANAGEMENT
342 42ND ST S
FARGO, ND 58103 USA

Contact: MELINDA PHAN

Phone: 714716961

FedEx Location Information

Express Station ID: FARA

Ground Terminal Id: FARG

Sales Professional : Jean M. Broad

Phone Number : 701-799-0087

Field Engineer: Michelle Duda

Phone Number : 651-337-1898

Product Information

Commodity Code : 24 **UN No :** 1845 **Model Number:** 1 **Pcs. Per Pkg:** 10

Values : 45.00 **Product Description:** MAC -

Packaging Information

Size : L (in): 9.5 **W (in):** 9.5 **H(in):** 8 **Wt (lb):** 6.4 **Outer Container Type:** Corrugated

Container Specs: C-Flute Singlewall 200 Burst Test

Other Outer Info: RSC style

Inner Packaging I: Kevothermal Vacuum Insulation Panels **Inner Packaging II:** glass vials **Sealing Method:** PST on top middle seam, duct tape on bottom middle seam

Other Inner Info: Kevothermal Vacuum Insulation Panels, untied plastic bag, 10-glass vials with screw caps with plastic die cut, coolant was water absorbent bead, temperature sensor in zip lock bag.

Test Procedures Completed

Test Type : Domestic - FedEx

Drop Height (in) : 30 inches **Drop Sequence :** One Set Free - Fall

Drop Results: Package Failed - See "Comments" section on page 2

Compression Factor: 5 **Compression Load (lbf) :** 316

Compression Results: Meets Minimum Specifications

Vibration Profile: Domestic FedEx **Vibration Duration:** 60 Minutes Rotary

Vibration Results: Package Failed

Impact Sequence: **Impact Velocity (ft/s):**

Test Results

Result:	Failed

Definitions of Results

Passed:	A package, with article, that has passed all the Fedex Standard Testing Procedures. For commodities restricted under Liabilities Not Assumed in the Fedex Service Guide, Service Guide Terms and Conditions will take precedence.
Failed:	A package, with article, that has failed all FedEx Standard Testing Procedures.
Pending:	A package, with article, that has been tested to all FedEx Standard Test Procedures. Confirmation of results is subject to customer inspection.

Comments and Packaging Recommendations*

Prototype Packaging. FedEx Package Testing Procedures for shipment under 150 lbs., or ISTA 6-FedEx-A, were followed for this test.

Initially the test package failed due to the use of duct tape for tape sealing closure. Some of the glass vials came loose from the plastic containment holder. Also some of the screw caps were loose on the glass vials. Poly bag was not tied.

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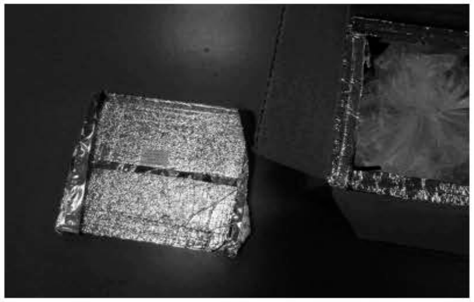
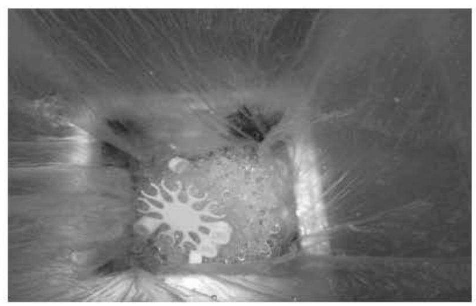
Reference FedEx General Packaging Guidelines: http://www.fedex.com/us/services/pdf/packaging/GrlPkgGuidelines_fxcom.pdf

Photos / Drawings (if Applicable)




J3894-ITEM1
9x9x1 VIP-2
MfgDate: 10/14/14
SHIFTA



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Toll Free 800.633.7019 option 5 Fax : 901.492.7278

Service Information

PDD Contact : John Purinton **Test or Evaluation :** Test **Report Number :** 55101

Received Date : 11/11/2014 **Processed Date :** 11/18/2014 **Express**

Customer Information

Acct # : 212752797
CLINICAL SUPPLIES MANAGEMENT
342 42ND ST S
FARGO, ND 58103 USA

Contact: MELINDA PHAN

Phone: 714716961

FedEx Location Information

Express Station ID: FARA

Ground Terminal Id: FARG

Sales Professional : Jean M. Broad

Phone Number : 701-799-0087

Field Engineer: Michelle Duda

Phone Number : 651-337-1898

Product Information

Commodity Code : 24 **UN No :** 1845 **Model Number:** 1 **Pcs. Per Pkg:** 10

Values : 45.00 **Product Description:** MAC -

Packaging Information

Size : L (in): 9.5 **W (in):** 9.5 **H(in):** 8 **Wt (lb):** 6.2 **Outer Container Type:** Corrugated

Container Specs: C-Flute Singlewall 200 Burst Test

Other Outer Info: RSC style

Inner Packaging I: Kevothermal Vacuum Insulation Panels **Inner Packaging II:** glass vials **Sealing Method:** PST on top middle seam, duct tape on bottom middle seam

Other Inner Info: Kevothermal Vacuum Insulation Panels, untied plastic bag, 10-glass vials with screw caps with plastic die cut, coolant was water absorbent bead, temperature sensor in zip lock bag.

Test Procedures Completed

Test Type : Domestic - FedEx

Drop Height (in) : 30 inches **Drop Sequence :** One Set Free - Fall

Drop Results: Package Failed - See "Comments" section on page 2

Compression Factor: 5 **Compression Load (lbf) :** 316

Compression Results: Meets Minimum Specifications

Vibration Profile: Domestic FedEx **Vibration Duration:** 60 Minutes Rotary

Vibration Results: Package Failed

Impact Sequence: **Impact Velocity (ft/s):**

Test Results

Result:	Failed

Definitions of Results

Passed:	A package, with article, that has passed all the Fedex Standard Testing Procedures. For commodities restricted under Liabilities Not Assumed in the Fedex Service Guide, Service Guide Terms and Conditions will take precedence.
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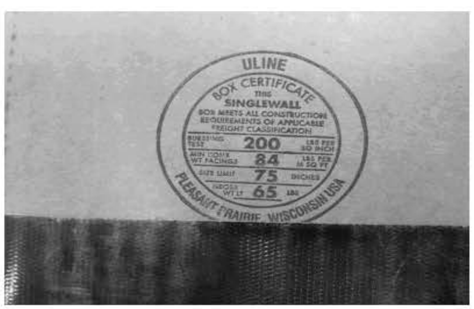
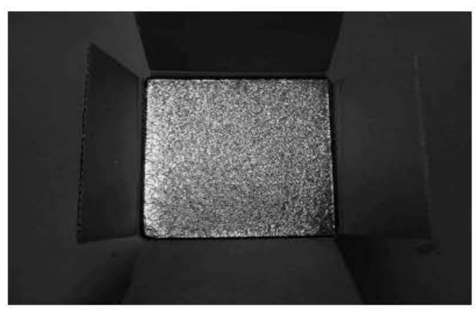
Reference FedEx General Packaging Guidelines: http://www.fedex.com/us/services/pdf/packaging/GrlPkgGuidelines_fxcom.pdf

Photos / Drawings (if Applicable)






J3894-ITEM1
9x9x1 VIP-2
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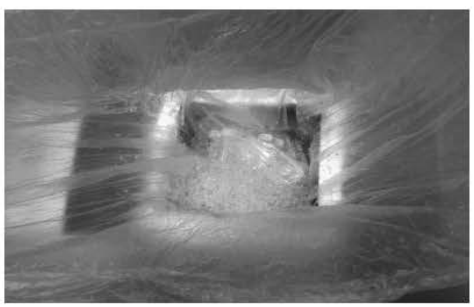

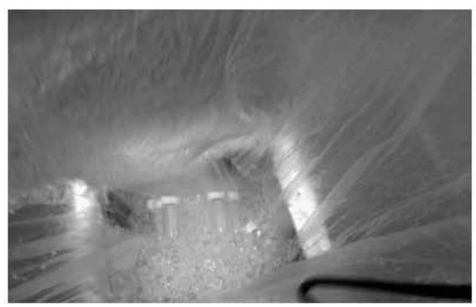

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