Temperature Controlled Packaging: Considerations You Might Not Know

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Introductions

Ken Maltas

- Director of Engineering
  - 7 years cold chain, 35 years medical packaging
- Bradley University – BSIE
- Purdue University – MSIE
- Applications and New Product Development

Iftekhar Ahmed

- Design Team Lead
- Thermal Flow & Design Analysis
  - Over 20 years
- University of Michigan:
  - Thermal Sciences & Numerical Techniques
- Developed & Implemented Engineering Simulation Tools
  - Temperature Assurance Packaging
Agenda

- Company Overview: Sonoco, ThermoSafe, & ISC Labs
- Expectations From Seminar
- Discussion Points
  - Temperature spread based on refrigerant coverage
  - Conditioning – Cold Shock and Refrigerant Bench Times
  - Product Mass and Temperature
  - Opening up Product Temperature Range
  - Ambient Profile and Cost
  - Universal vs Seasonal Solutions
  - Shipping a Box on its Side
  - Cost versus Insulation Choice
  - Cost Versus PCM Choice
- Q&A
• Founded in 1989, global leader in innovative design & testing services.

• Multiple U.S. locations for convenient access with additional engineering support located in Europe.

• ISTA certified lab following cGMP based methodologies, conforming to PDA technical report 39 and ASTM standards.

• Maintain the industries most advanced thermal modeling capabilities.
BEST PRACTICES: Quality by Design (QbD)

DEFINE THE PROBLEM
Define the Problem

Establish a team

- Who should be included? What business functions?
  - Engineering/ Packaging
  - Procurement
  - Regulatory
  - Logistics
  - Operations/ Manufacturing
  - Quality/ Validation
  - Marketing
  - End Customer?
  - Other?
### Factors For Team to Consider

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Performance Needs</strong></td>
<td>• Duration, Temperature, Payload, Ambient Profiles</td>
</tr>
<tr>
<td><strong>Regulatory Needs</strong></td>
<td>• Reference Documents, Available Excursions</td>
</tr>
<tr>
<td><strong>End User Needs</strong></td>
<td>• Packout Configuration: Universal / Seasonal,</td>
</tr>
<tr>
<td></td>
<td>• Ease of use, # of components, weight, pack-out time, dimensional, etc.</td>
</tr>
<tr>
<td><strong>Pricing (value) need</strong></td>
<td>• Package Cost, freight cost, physical weight vs dimensional weight</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>• Ergonomics</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>• Tolerances / testing requirements</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>• Sustainability, shipping lanes, return-reuse, conditioning, data monitoring, etc.</td>
</tr>
</tbody>
</table>
Factors to Consider

- Distinguishing Between Various Factors
  - Cost vs Quality
  - Packaging Cost vs Shipping Costs
  - Costs vs Ergonomics
  - Sustainability
  - Use of Excursion Data vs Design Complexity
  - Ease of Use vs Cost
  - Single use vs Return/Reuse

- Different Stakeholders / Different Views
TEMPERATURE SPREAD BASED ON REFRIGERANT COVERAGE
Refrigerant Configurations

6 sided

4 sided

2 sided
Product probe locations

- Top Center
- Top Corner
- Midside
- Center
Top Center Probe

Graph showing temperature trends over time with different markers for different conditions.

Legend:
- 2 C
- top-center-6sided
- top-center-4sided
- 8 C
- top-center-2sided
- ISC Silver Summer
Top Corner Probe
Center Probe

Graph showing temperature variations for different probe configurations over time.
Midside Probe

![Graph showing temperature changes over time for different conditions: 2 C, 8 C, Midside-6sided, Midside-4sided, Midside-2sided, and ISC Silver Summer. The graph includes a grid for reference.]
Product Temperatures in Specification

<table>
<thead>
<tr>
<th>Design Configuration</th>
<th>Top Center Probe</th>
<th>Top Corner Probe</th>
<th>Center Probe</th>
<th>Midside Probe</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-sided</td>
<td>72</td>
<td>72</td>
<td>72</td>
<td>72</td>
</tr>
<tr>
<td>4-sided</td>
<td>54</td>
<td>48</td>
<td>42</td>
<td>48</td>
</tr>
<tr>
<td>2-sided</td>
<td>35</td>
<td>7</td>
<td>29</td>
<td>4</td>
</tr>
</tbody>
</table>
EF6040 pallet, product probe temperatures by location
CONDITIONING – COLD SHOCK AND REFRIGERANT BENCH TIMES
Preventing Cold Shock

- Cold Shock is the rapid decline in product temperature during the initial packout phase, when frozen refrigerant comes into contact with the product.
  - How to prevent cold shock
    - Refrigerated gels or bricks
    - Buffer pads e.g. corrugate, EPS, bubble wrap
    - Bench time for frozen refrigerants
    - PCMs with phase temperatures above cold shock temperatures
Using PCMs to prevent Cold Shock

- **PCM vs. water-based gel pack**
  - PCM phases at 4°C → keeps product >2°C
  - Water-based gel phases at 0°C → product drops below 2°C
Effect of Bench Time on Refrigerants

- Higher Refrigerant mass requires more bench time for warm up
- Bench time at room temperature can help reduce cold shock
PRODUCT MASS & TEMPERATURE
Impact of Mass and Density

- The rate of change of thermal energy per unit volume
  - To achieve the same change in temperature a greater mass (density) requires a greater rate of change of thermal energy.

\[ \dot{E} = \rho c_p \frac{\partial T}{\partial t} \, dx \, dy \, dz \]
Probe Locations and Methodology

- Product packaging and thermal mass
  - Small thermal mass will make product temperatures much more responsive to ambient conditions

- 5 ml vial with 1 ml to 3 ml fill
- 75 ml Bottle
- 10 ml bottle
Probe Locations and Methodology

- Product packaging and thermal mass
Product Load Selection

- Thermal considerations for Product Load selection
  - Thermal Mass or Capacitance
  - Effect of Conduction and Convection

- Product Loads for Testing
  - Bracketing Product Mass for Testing
    - Minimum Load
    - Maximum Load
    - Empty container
Product Load Selection

- Thermal Mass or Capacitance
  - Defined as the product of mass and specific heat $\rho \times C_p$
  - Determines the rate of product thermal response to changes in ambient conditions

Product with Low Thermal Capacitance will respond more quickly to cold shock and change in ambient conditions
Product Load Selection
Effect of Conduction & Convection

Top Ambient = 5 C

Max Product Temperature = 17 C
Corepack filled with Dunnage

Side Ambient = 22 C

Max Product Temperature = 11 C
Corepack filled with Air

Convection Currents
Product Load Selection

- Difference between Maximum, Minimum and Empty Product Loads
- Winter Ambient indicates that Empty Load Probe will have the lowest or worst case temperature.
Product Load Selection

- Difference between Maximum, Minimum and Empty Product Loads
- Summer Ambient indicates that Empty Load Probe will have the highest or worst case temperature.
OPENING UP PRODUCT TEMPERATURE RANGE
Effect of Product Temperature Range

- CRT Case Study
- The narrower the product temperature criteria the more challenging is the thermal design, more refrigerants, more insulation

<table>
<thead>
<tr>
<th>Temperature Range</th>
<th>Refrigerant Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>20°C - 25°C</td>
<td>24 lbs of Refrigerant</td>
</tr>
<tr>
<td>15°C - 30°C</td>
<td>18 lbs of Refrigerant</td>
</tr>
<tr>
<td>5°C - 30°C</td>
<td>12 lbs of Refrigerant</td>
</tr>
</tbody>
</table>
Effect of Product Temperature Range

- Refrigerated Case Study

![Graph showing temperature variations over time for different durations and temperatures.](image-url)

- 61-Hr, 2-8°C
- 76-Hr, 2-10°C
- 98-Hr, 2-15°C

Performance Duration 48-hr: 2.9°C to 7.7°C
Test Duration 99-hr: 2.9°C to 16.6°C
AMBIENT PROFILE AND COST
Effect of Ambient Profiles on Package Design

- An more extreme Ambient Profile will have the following impact on TAP design:
  - More refrigerant weight
  - More components
  - Higher insulation e.g. thickness, R-value
  - Higher Cost
  - Larger container dimensions
Effect of Ambient Profiles on Package Design

Ambient Profiles

Elapsed Time (Hours)

Temperature (°C)

-20.0

-10.0

0.0

10.0

20.0

30.0

40.0

50.0

ISC Gold Summer
ISC Silver Summer
ISC Gold Winter
ISC Silver Winter
Effect of Ambient Profiles on Package Design

- ISC Gold profile vs. ISC Silver profile, 48 hours, 2°C to 8°C, Universal

<table>
<thead>
<tr>
<th>Ambient Profile:</th>
<th>ISC Silver Universal</th>
<th>ISC Gold Universal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payload Volume (L):</td>
<td>16.4</td>
<td>16.4</td>
</tr>
<tr>
<td>Shipper O.D. Volume (L):</td>
<td>109.7</td>
<td>141.2</td>
</tr>
<tr>
<td>Number of Components:</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>Weight (lbs):</td>
<td>31.6</td>
<td>40.5</td>
</tr>
<tr>
<td>Dimensional Weight (lbs):</td>
<td>40</td>
<td>52</td>
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</table>
UNIVERSAL VS SEASONAL SOLUTIONS
Profile Bracketing

- Packout Configuration
  - Seasonal – One Ambient Profile
    - Simpler Packout
    - Lower Cost
    - Different packouts for each season
    - Possibility of Product Excursions if Seasonal Designs are not transitioned at the right time
  - Universal – One Summer and One Winter Ambient Profile
    - One packout for all seasons
    - Higher Cost
    - Product Temperature Stability year round
  - Bracketed – Upper and Lower Ambient Profiles for Each Season
    - Compromise between Seasonal and Universal
    - Better product stability due to transition between seasons
    - Different packouts for each season
Profile Bracketing

![Hot Gold Graph](image)
Profile Bracketing

Bracketed Summer Profile

- Hot
- Gold cool during warm
Profile Bracketing

Bracketed Winter Profile

Cold Gold  Cold warm during cool
Profile Bracketing

Universal Hot and Cold

Cold Gold  Hot Gold
# Profile Bracketing: Total Cost of Ownership

<table>
<thead>
<tr>
<th></th>
<th>Stratta™, Universal</th>
<th>Stratta, Summer</th>
<th>Stratta, Winter</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System Weight</strong></td>
<td>30 lbs</td>
<td>24 lbs</td>
<td>22 lbs</td>
</tr>
<tr>
<td><strong>International Dim Wt.</strong></td>
<td>31 lbs</td>
<td>27 lbs</td>
<td>27 lbs</td>
</tr>
<tr>
<td><strong>System Price</strong></td>
<td>$81</td>
<td>$54</td>
<td>$54</td>
</tr>
<tr>
<td><strong>Shipping Cost</strong></td>
<td>$62</td>
<td>$54</td>
<td>$58</td>
</tr>
<tr>
<td><strong>Total Cost</strong></td>
<td>$143</td>
<td>$108</td>
<td>$106</td>
</tr>
</tbody>
</table>
SHIPPING A BOX ON ITS SIDE
Impact of Orientation

- Experience with a small parcel shipping system qualified in the upright orientation only
Impact of Orientation

Carrier A

“Place shipping labels on the package’s largest surface. While we cannot ensure compliance with markings such as “Up” arrows or “This End Up,” properly placing the shipping label increases your chance for the preferred orientation.”

Carrier B

“Note: Carrier B does not provide special handling for packages with "Fragile", package orientation (e.g., "UP" arrows or "This End Up" markings), or any other similar such markings.”
Impact of Orientation

At local hub
- Upright - In container for air transport

At main sort facility
- Upright temporarily
- Loaded on delivery truck
- Upright on truck for final delivery
Case Study 1

- EPS Shipper with six sided frozen water based Polar Packs
Case Study 1

Case Study 1 - Winter

Temperature (°C) vs. Time (Hours)

- Upright Top Corner Max
- Upright Top Center Max
- Upright Top Side Empty
- Upright Top Center Empty
- Win Silver
- Upright Min 3
Case Study 1

Cast Study 1 - Summer

Temperature (°C)

Time (Hours)

- Upright Min 1
- Upright Empty Bottom Corner 3
- Upright Max Bottom Corner 4
- Upside Down Empty Top Center 4
- Upside Down Max Top Center 5
- Upside Down Min 6

SONOCO
Design & Testing Services

SONOCO THERMOSAFE™
Case Study 2

- EPS shipper with two sided coverage
- Utilizes both refrigerated and frozen Polar Packs
Case Study 2

Case Study 2 - Winter

Temperature (°C)

Time (Hours)

- Upright Min 1
- Upright Empty Top Center 2
- Upright Max Bottom Corner 3
- Long Side Down Max Bottom Corner 1(2)
- Long Side Down Empty Top Center 2
- Long Side Down Empty Bottom Corner 2
- Long Side Down Min 3
Case Study 2
COST VS INSULATION CHOICE
Insulation Type Comparison

Example: EPS vs PUR vs VIP

R-Value

Package Size

Weight

Container Cost

Total Cost Can Be Reduced

Can Be Reduced
Insulation Type Comparison

Example: EPS vs PUR vs VIP

- EPS PACKAGING Size
  - PAYLOAD 1L
  - 32 kgs

- PUR PACKAGING Size
  - PAYLOAD 1L
  - 18 kgs

- VIP PACKAGING Size
  - PAYLOAD 1L
  - 9 kgs

5” PUR = 1” VIP
# Total Cost of Ownership: Case Study

<table>
<thead>
<tr>
<th>2-8C / 96-Hours, Univ.</th>
<th>PUR</th>
<th>VIP</th>
<th>Stratta™ (EPS/VIP)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System Weight</strong></td>
<td>38 lbs</td>
<td>32 lbs</td>
<td>30 lbs</td>
</tr>
<tr>
<td><strong>International Dim Wt.</strong></td>
<td>55 lbs</td>
<td>24 lbs</td>
<td>31 lbs</td>
</tr>
<tr>
<td><strong>System Price</strong></td>
<td>$92</td>
<td>$118</td>
<td>$81</td>
</tr>
<tr>
<td><strong>Shipping Cost</strong></td>
<td>$110</td>
<td>$64</td>
<td>$62</td>
</tr>
<tr>
<td><strong>Total Cost</strong></td>
<td>$202</td>
<td>$182</td>
<td>$143</td>
</tr>
</tbody>
</table>
COST VS PCM TYPE
PCM Type Comparison

Example: Water vs Advanced PCM

- Advanced PCM
- Water
- Package Size
- Weight
- Container Cost
- Total Cost Can Be Reduced

Can Be Reduced
PCM Type Comparison

Example: Water vs Advanced PCM

Packaging Size w/Advanced PCM

Packaging Size w/water

25 kgs

12 kgs
Thank You!