

LIFTING THE LID ON PASSIVE PACKAGING

A behind-the-scenes look at a
high-performance shipper



Introduction

The risks to temperature excursions inherent in global logistics are now well-documented. With pharmaceutical products becoming ever-more sophisticated and specialised, supply-chain technologies and processes find themselves on a similar trajectory, adapting and becoming more advanced in order to support individual packaging systems needs.

You will know about the time-temperature conundrum where the transport and storage of medical products are concerned. And you will know that properly-engineered solutions play a critical part in the freightage process, adding a layer of protection in transit. But what exactly are the dynamics of a cold chain package in transit? What are the mechanics behind the stability of their temperature? And how do they mitigate the temperature control problems faced in transit?

This paper takes a closer look at what constitutes a high-end, cold chain solution.



There are industry standards to be met (ISTA 7D, ISTA 7E, WHO), so careful selection of materials and design by the manufacturer is fundamental.

Packaging for performance

One of the most critical investments in protecting a temperature sensitive payload is in a packaging solution that does its job – no matter what the circumstances. A first-rate, TCP (Temperature Control Packaging) systems must work independently of the physical facilities available over the duration of a shipment. The aim? Total temperature stability – even when storage conditions fluctuate beyond expectations.

An ambient challenge or profile is often specified by the customer and will be a representation of what their shipping lane is likely to experience in terms of time and temperature. A quality packaging system is designed to accommodate these.

There are industry standards to be met (ISTA 7D, ISTA 7E, WHO), so careful selection of materials and design by the manufacturer is fundamental. Only when the correct combination of thermal packaging materials (insulation and phase change materials) are brought together, is a temperature-stable environment created.

Normalising/assessing thermal stress – with Kelvin Hours

With ambient profiles defined early in the design process, the packaging system must have its performance

thoroughly evaluated through environmental chamber testing. When appraising an ambient profile, thermal packaging designers can use tools such as Kelvin Hours to quickly understand how much thermal stress a profile will present to a shipper. Kelvin Hours account for both time and temperature exposures. Basically, the hotter the temperature and longer the duration, the higher the Kelvin Hour score.

Let's look at an example.

If we were to subject a packaging system (which has been designed to maintain an internal temperature of +5°C) to an ambient temperature of +30°C, let's say for 48 hours, the Kelvin Hour score would be calculated as follows:

1. Thermal Stress (Kelvin) is the difference in temperature between the packaging system's payload temperature and the external ambient temperature. So, +30°C minus +5°C = 25 Kelvin.
2. Multiply the Kelvin stress by the profile duration, in this case 48 hours. So, 25 x 48 = 1,200K.Hrs

In the event where multiple profiles have to be overcome by the packaging system design, bracketed temperature / Kelvin Hour scores are outlined for the system performance to meet.

Looking at your profile

There are multiple performance considerations that come into play in the packaging system design process. The first of these – temperature ranges – comes with a simple rule: The narrower the temperature range and longer the duration, the more challenging it becomes to design a compliance packaging system.

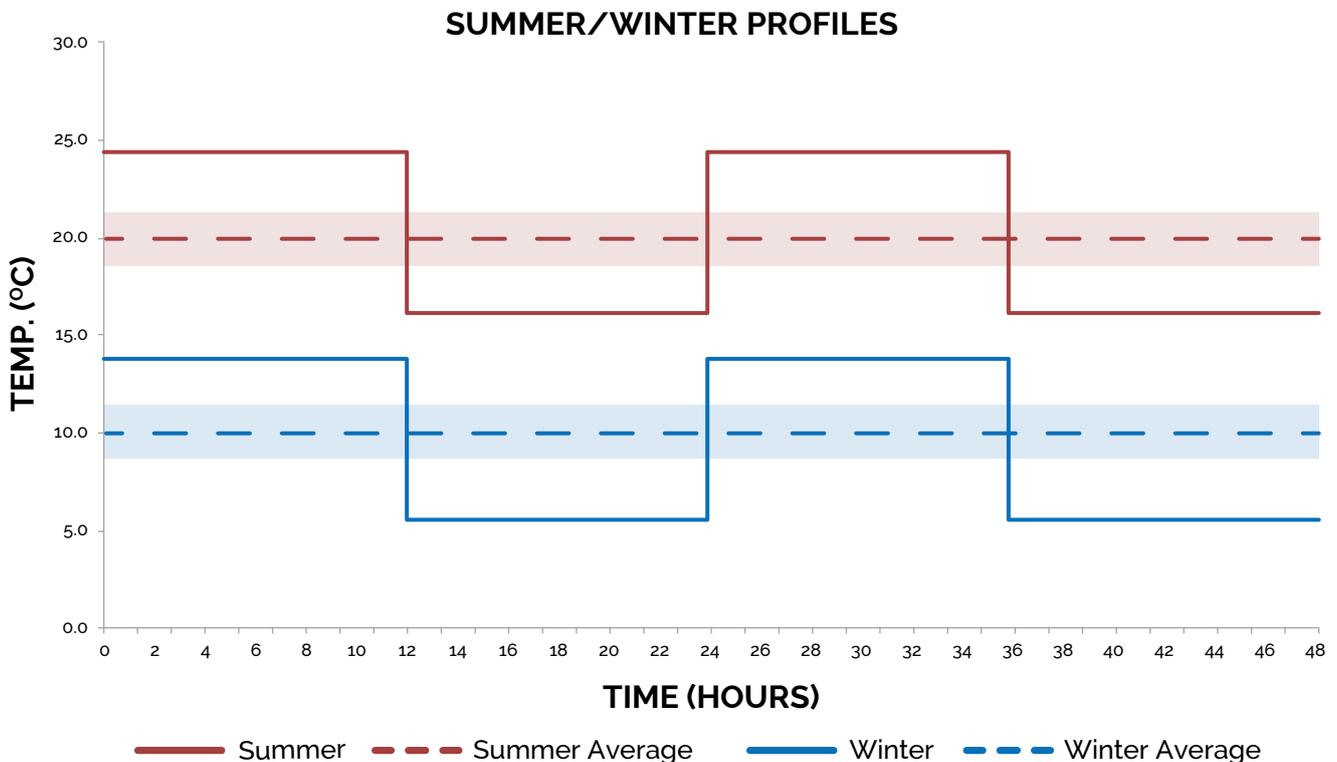
A. The Seasonal Profile

Most traditional thermal packaging systems utilise water-based coolants that are designed to cope with a range of average ambient temperatures. Ideal for temperate summer and winter shipping, we find a fairly narrow field of variation due to their material properties.

These packaging systems tend to have an operating bracket of around 10 Kelvin, meaning that if you were designing a 48-hour, +2°C to +8°C system, you might chose profiles as shown in the table below and in figure 1:

| PROFILE | AVERAGE TEMPERATURE | PROFILE RANGE | KELVIN HOUR |
|-------------------|---------------------|----------------|-------------|
| Summer - 48 hours | +20°C | +24°C to +16°C | 720 |
| Winter - 48 hours | +10°C | +14°C to +6°C | 240 |

Fig 1. Simple Seasonal Ambient Profiles



While systems designed for seasonal profiles are fit for purpose, their effectiveness can diminish when asked to function outside their stated profile. Should there be a chance of ambient conditions moving into hotter or cooler territories, seasonal pack-outs can be tailored accordingly – and they can look good on paper. However, quite large and heavy pack-outs will often be costly to ship. Of even more concern are the excursion rates, which typically reach around 30%. With such fluctuations, a temperature excursion in the payload will likely occur. More reliable options are available.

B. The Bracketed Profile

This profile is designed to offer more room for manoeuvre. The Bracketed Ambient Profile addresses the problem that arises when shipping along 'hot-to-cold' or 'cold-to-hot' lanes. Naturally, temperature ranges in such circumstances are more variable.

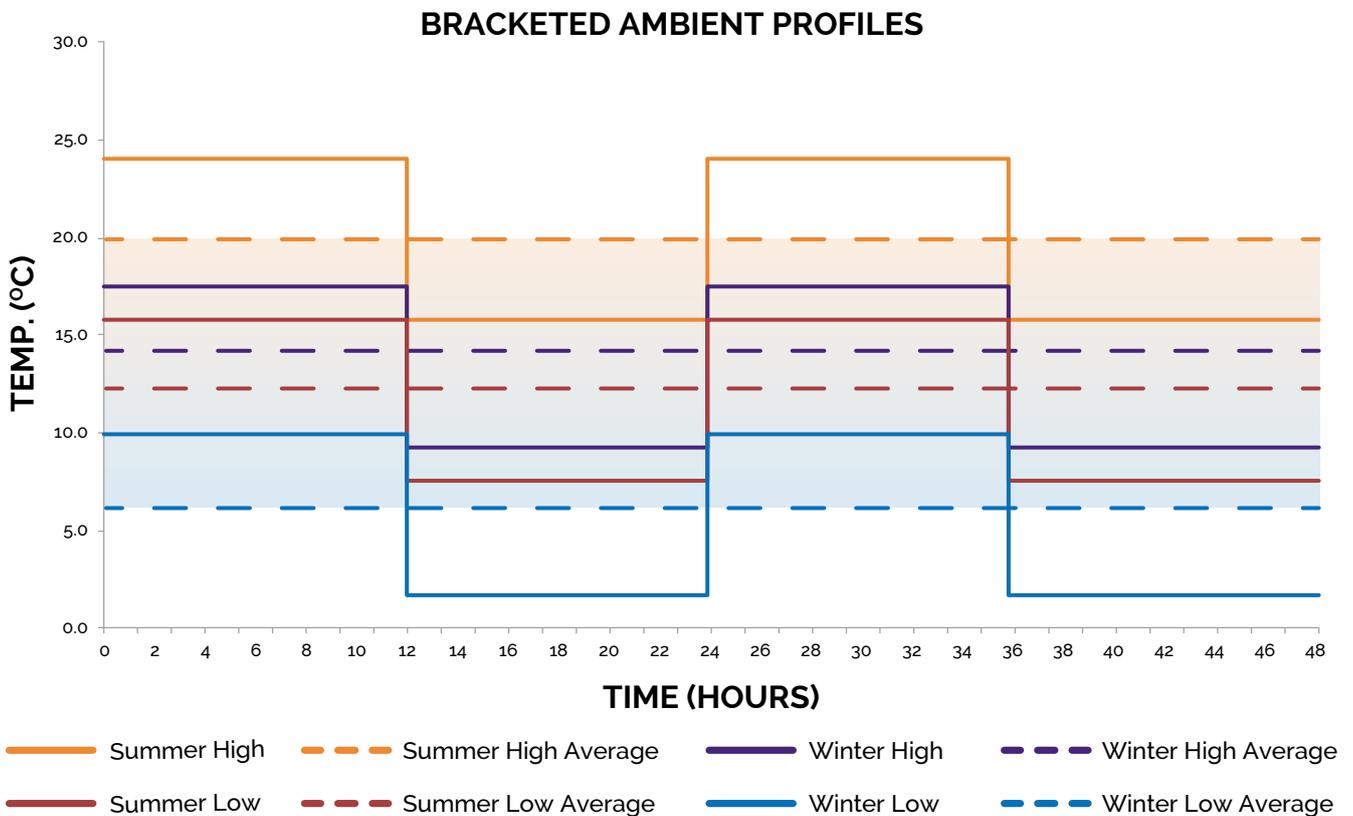
Similarly, at transitional times of the year such as Spring and Autumn, imbalances can occur, where day-to-day temperatures in one region can

differ greatly from those in another. With weather around the globe becoming increasingly erratic and extreme, this issue is becoming ever-present.

So how do we create more robust packaging systems, capable of dealing with the challenges posed by seasonal temperature swings? One method is to create Seasonal Bracketed Ambient Profiles. Building on our example above, we can create a Summer High/Low and Winter High/Low challenge. Calculations are shown in the table and figure 2 below:

| PROFILE | AVERAGE TEMPERATURE | PROFILE RANGE | KELVIN HOUR |
|------------------------|---------------------|----------------|-------------|
| Summer High - 48 hours | +20°C | +24°C to +16°C | 720 |
| Summer Low - 48 hours | +12°C | +16°C to +8°C | 336 |
| Winte Highr - 48 hours | +14°C | +18°C to +10°C | 432 |
| Winter Low - 48 hours | +6°C | +10°C to +2°C | 48 |

Fig 2. Bracketed Ambient Profiles





In essence, should you use your Summer configuration and it experiences cool shipping conditions, it will maintain payload temperatures at the correct range.

By adopting Bracketed Ambient Profiles in our packaging system development, we are incorporating a further layer of thermal robustness. Again, there are pros and cons. You could safely expect the rate of excursions to drop to around the 15% mark. But a heavier, larger and more expensive packaging system will be generated in the process.

Looking at the charts on the previous page in more detail, you'll notice that the Summer Low and Winter High profiles overlap. This allows either configuration of the system to perform when exposed to that temperature range. In essence, should you use your Summer configuration and it experiences cool shipping conditions, it will maintain payload temperatures at the correct range. Likewise, the Winter configuration is capable of performing against warmer conditions. These scenarios often occur during the transitional seasons.

With a Bracketed Ambient Profile still potentially experiencing 15% excursions on shipments, we have to ask ourselves what more can be done to make the ambient profiles – and therefore the packaging systems – even more robust.

We cannot ignore the fact that there still remains a possibility of unforeseen obstacles that would need to be overcome.

While we may choose our correct configuration (Summer or Winter), an ambient challenge lurks around every corner – where a packaging system could face even hotter or colder temperatures than had been anticipated. This gives rise to 2 principle scenarios.

Scenario 1 – Wouldn't it be easier to pack out a seasonal shipper with just one configuration that's capable of functioning all year round?

Scenario 2 – In the face of hotter and colder profiles, couldn't we just widen the ambient challenge, taking into account all potential temperatures in one hit?

Let's tackle both scenarios in their own right. (But we will circle back because the two are ultimately linked.)

C. The All-Year-Round Profile

The quick answer is yes, year-round pack-outs are possible. But it may not surprise you that this solution comes with a caveat – traditional thermal packaging materials aren't up to the job.

We learnt earlier that traditional packaging systems have an operating range of around 10 Kelvin. Although this figure can be marginally modified by adding or removing frozen coolants and balancing them with refrigerated coolants, the 10 Kelvin performance bracket essentially remains the same.

Moving to a year-round pack-out affords a hike in performance capability – the shipper will need to cope with operating brackets that could scale to 30 Kelvin.

This is where Scenario 2 kicks in.

For any year-round pack-out to function effectively, it must be able to endure a far wider range of ambient temperatures. As the name suggests, this means any time of the year, just about anywhere.

There's no question that operationally at least, this simplifies matters. Not to mention significantly reducing excursion rates. The question is, how is this achieved?

The key lies in the use of advanced Phase Change Materials (PCM) that freeze and thaw within the required temperature range for the product being shipped.

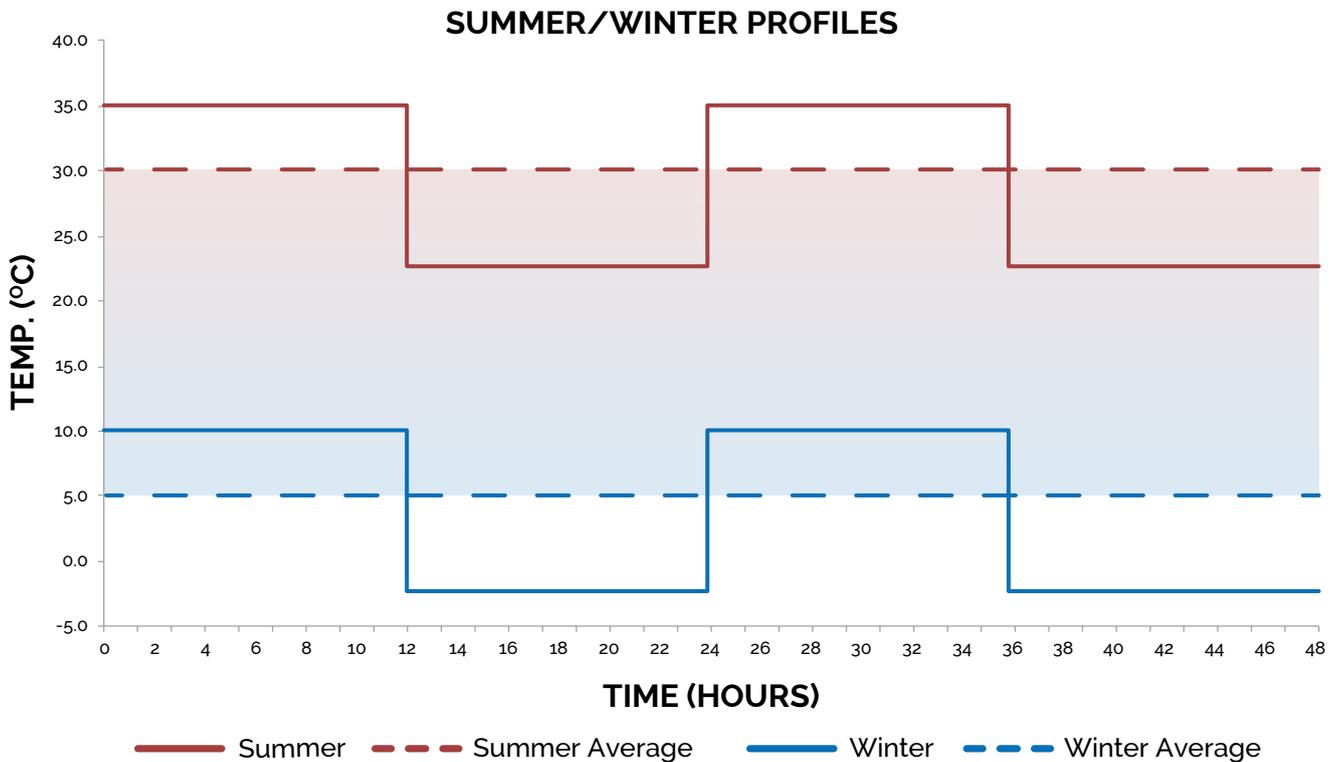
Not only can the design of these packaging systems be considerably more thermally robust, but when combined with advanced insulation materials they will be palpably smaller.

| PROFILE | AVERAGE TEMPERATURE | PROFILE RANGE | KELVIN HOUR |
|----------------|---------------------|----------------|-------------|
| Summer Extreme | +30°C | +35°C to +25°C | 1200 |
| Winter Extreme | +5°C | +10°C to +0°C | 0 |

The net result is that a system with a single pack-out and a year-round ambient profile greatly reduces the potential risk of excursion.

From my own experience, excursions rates of less than 0.01% can be achieved. There's an added bonus too. Smaller, more compact packaging design will lower the outlay on shipping costs.

Fig 3. Year-round Ambient Profiles



Moving forward

When we make a reasonable assessment of the packaging system options that are now available, we can safely assume that thermal performance is somewhat subjective, yet by no means impossible to ascertain.

Through the use of new metrics such as Kelvin Hours, we now have the capability to better define the performance level that a thermal packaging system needs to attain, in order to overcome changing ambient demands. By increasing the thermal challenge/Kelvin Hour range that the system can surmount, we're able to enhance its performance. And therefore reduce the risk of any temperature excursion.

In fact, at Softbox, it is the continued investment and innovation in product design that now allows us to offer a total range of temperature control packaging systems – one that has been recognised by our industry and made us the go-to vendor for the pharmaceutical industry.

Performance options provide you with the ability to specify and select packaging that is 'fit for purpose'. You have seen how the selection of the specification can drive the effectiveness of the packaging system. And you are now privy to the methods involved in creating the different ambient profiles. The only question that could remain is, which of these might suit your next shipment?

About the author

Richard Wood is Director of Digital Connected Technologies at Softbox Systems UK Ltd, the temperature control packaging systems company that maintains the cold chain for more than half of the world's top 50 pharmaceutical company. He is an authority in his field and has been designing and engineering innovative temperature control packaging systems for the past fourteen years.

To see the full range of packaging options that are available to you, go to www.softboxsystems.com



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