PELI BioThermal™

Managing the Challenges of Controlled Room Temperature Requirements in Cold Chain Pharmaceutical Distribution

The Challenge of Controlled Room Temperature Shipments

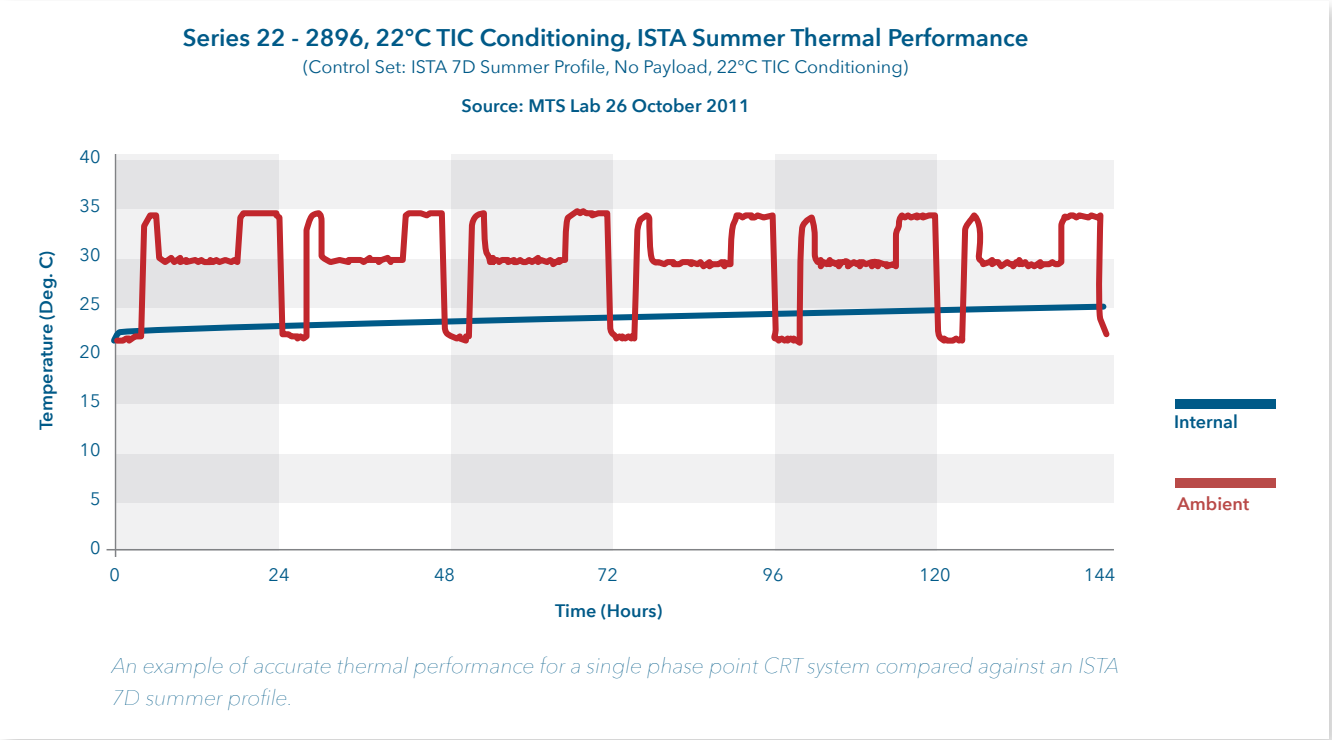
Controlled room temperature (CRT) cold chain packaging has many uses, but this versatile product also has challenges that are unique due to its requirement that the payload be kept between 15-25° Celsius. That's neither very hot nor very cold, so fluctuations in the ambient temperature above and below can occur often during the shipping duration. This will stress a CRT shipper, unless it's designed to deal with both warm and cool temperatures during its journey.

CRT shippers based on a variety of coolants have been in use for decades, but control of the payload space has really only been available as advanced phase change material (PCM) have been used as coolants. Control of the ambient space external to the shipper could aid in meeting the performance requirements needed for a CRT shipper, but the ambient space presents challenges to control that can't always be met, due to heat spikes or cold shocks in the external environment. PCM-based coolants offer predictable phase points, over water coolants, for the payload space.

Limitations of water-based coolant systems for CRT shipments

Water is inefficient for CRT range thermal protection and really just slows down the heat and is susceptible to cold shocks in cold ambient environments. The amount of control offered with water-based coolants is far less than with PCM coolants. This is due in part because the water is just being used as thermal mass and not actually undergoing a phase change within the CRT control range. Additionally, due to the amount of water and insulation required, water-based coolant systems are typically highly inefficient due to low payload volume ratios compared to weight and outer dimensions. CRT shippers using water coolants may work for short duration, controlled lane shipments, but this is limited by their payload inefficiency and short usable duration.

Using CRT shippers with a single phase point will work for controlled shipping lanes, where the ambient temperature is known (and consistently below or above the PCM phase point) or controlled around the shipper. However, if that control of the external ambient space can't be guaranteed, thermal protection with a single phase PCM may not protect the payload space from external environment temperature fluctuations that cross into both sides of the phase point. In particular, shipping through different seasons (particularly Autumn and Spring) can cause fluctuations in temperature during the trip, that will stress the performance of a CRT shipper to keep the payload at a constant temperature within the operating zone required by the payload. And shipping from a hot zone to a cold zone, will also present difficulties to a single phase point PCM coolant to keep the payload within the required temperature.

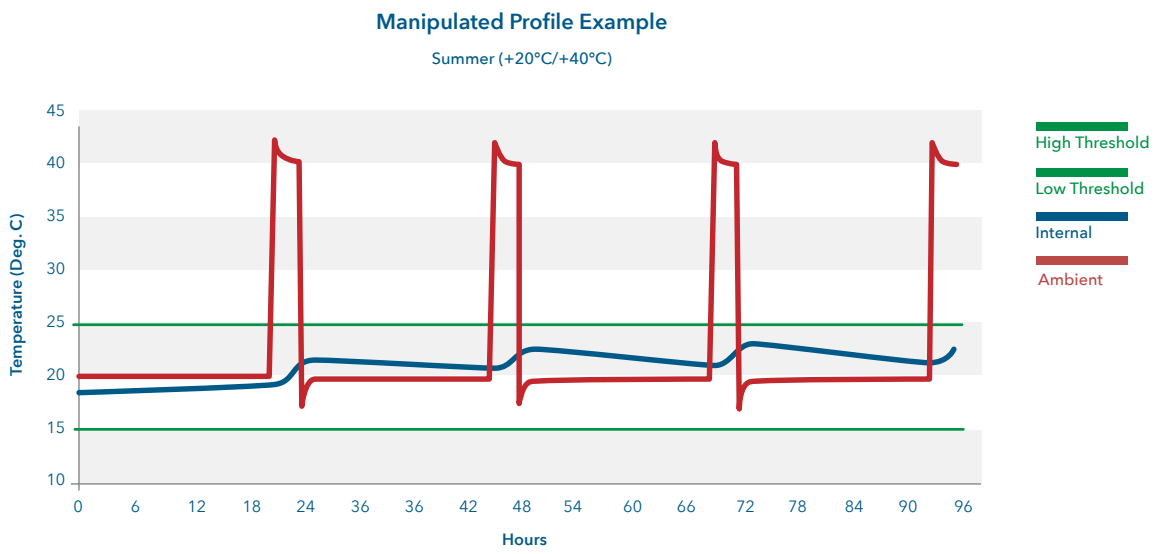


An example of accurate thermal performance for a single phase point CRT system compared against an ISTA 7D summer profile.

There are several ways that CRT shippers can be challenged by the ambient conditions and there are some solutions that will succeed for specific ambient conditions, and fail badly if those conditions are not as expected. Many single phase point CRT packaging solutions claim a single universal conditioning method all year round but typically have some shortcoming or method of manipulation to achieve this. Some of these are explored below.

Profile manipulation

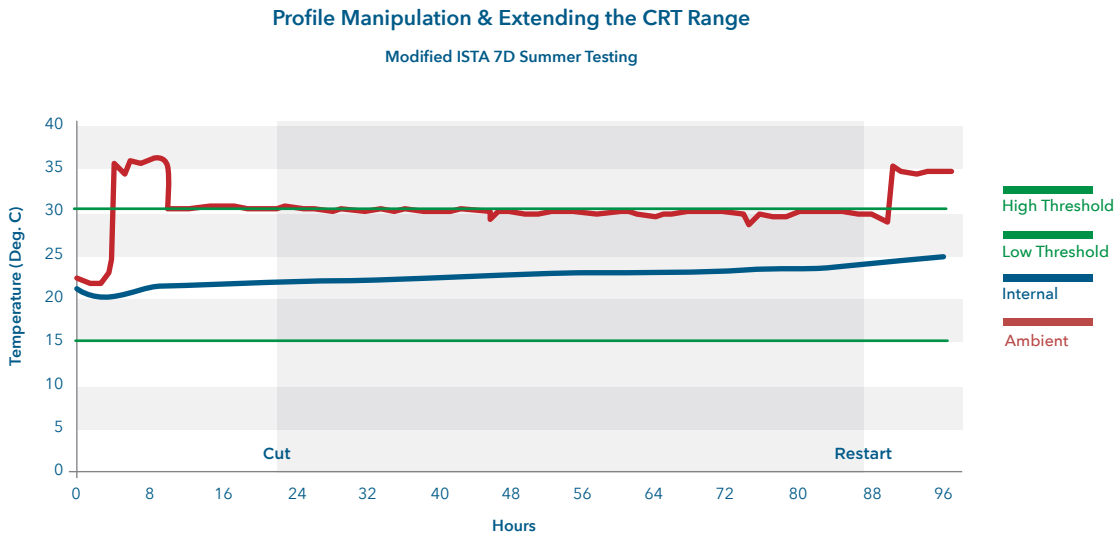
Often a set of summer and winter ambient challenge profiles is selected in such a manner to allow for single universal conditioning. Typically the winter profile is the more challenging ambient. A CRT shipper is often prepared to undergo a phase change to properly address the winter profile but not the summer. The summer profile is then selected or crafted in a manner that does not fully stress the shipper with ambient challenges above the high threshold range of +25°C. Qualifying in this manner allows for the claim of universal conditioning but in reality the packaging would potentially struggle in a rather warm external ambient condition.



An example of profile manipulation for a single phase point CRT system. The ambient temperature is within the centre for the allowable product temperature range for the majority of the time allowing for regeneration time between short stress spikes.

Extending the CRT Range

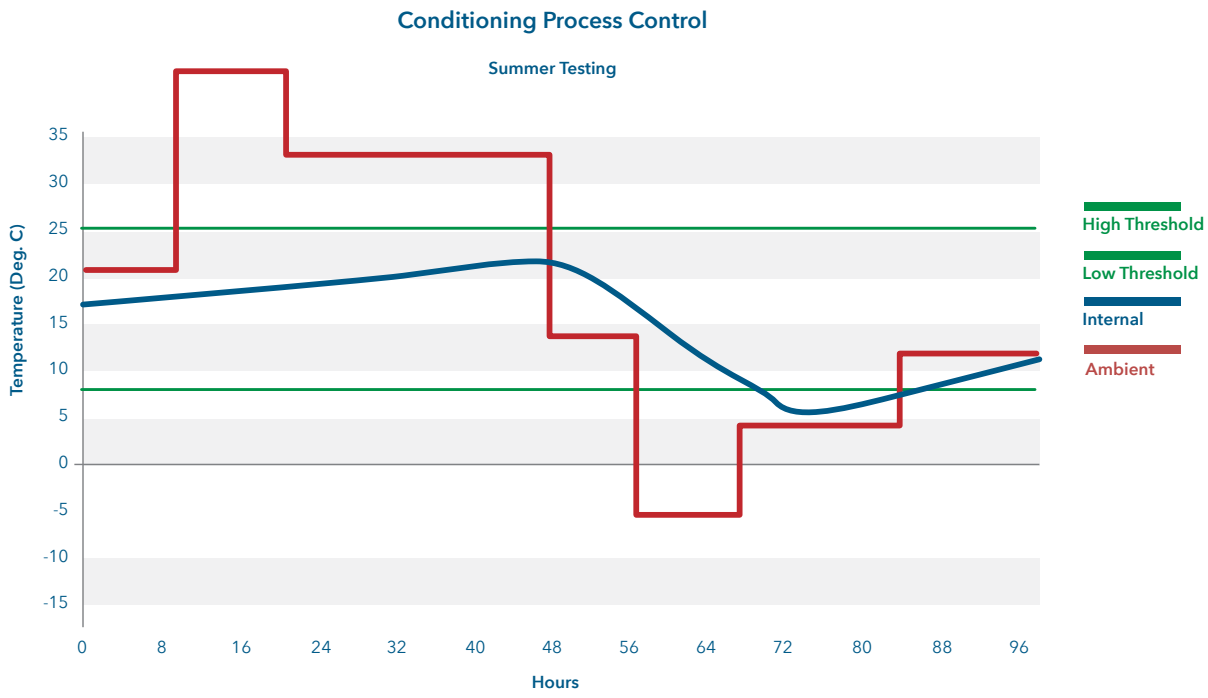
Often times the acceptable product hold range will be extended from 15-25°C to 15-30°C for a particular CRT system. While there are some CRT payloads that can withstand this widened range, it is most commonplace to encounter products requiring the 15° to 25°C range. The extension of the acceptable product range is often used in conjunction with the above mentioned profile manipulation to further lessen the impact of the chosen summer profile.



An example of extending the CRT range, as well as an example of profile manipulation, for a single phase point CRT system. The ambient temperature is manipulated and unrealistic with a steady temperature that is not outside the stated 15°C to 30°C product control range except the very beginning and end step.

Conditioning Process Control

There are several CRT system designs that do allow for universal conditioning but require the purchase and use of two completely separate PCM panel systems. In these systems, one set of panels has a phase point that is lower than the other set. Both panel sets are then placed in an environment that has a temperature between the two phase points. In this manner one set is liquid (cold ambient protection) and one set is frozen (hot ambient protection). While this system does allow for universal conditioning, it has two shortcomings. First, you have to buy two PCM panel sets. Second, you are still required to analyse the external ambient condition and decide whether to use the cold ambient panels or the hot ambient panels. Thus true universal conditioning is not achieved and the decision must be made for each shipment on which configuration will be used.



This profile shows a single phase point CRT system with coolants that are designed to perform well in hot weather, but it quickly fails when the ambient temperature drops below the lower end of the range.

A SIMPLE SOLUTION

Many of the above challenges can be resolved with a controlled shipping lane, where temperatures are well-known along each point in the journey and impact the CRT shipper in expected ways. However, in situations where the temperature not only can, but will fluctuate, a system with universal temperature protection is the best option. It eliminates concerns about shipping from hot zones to cold zones, vice versa or during seasons with significant temperature variation from day to day (particularly Autumn and Spring).

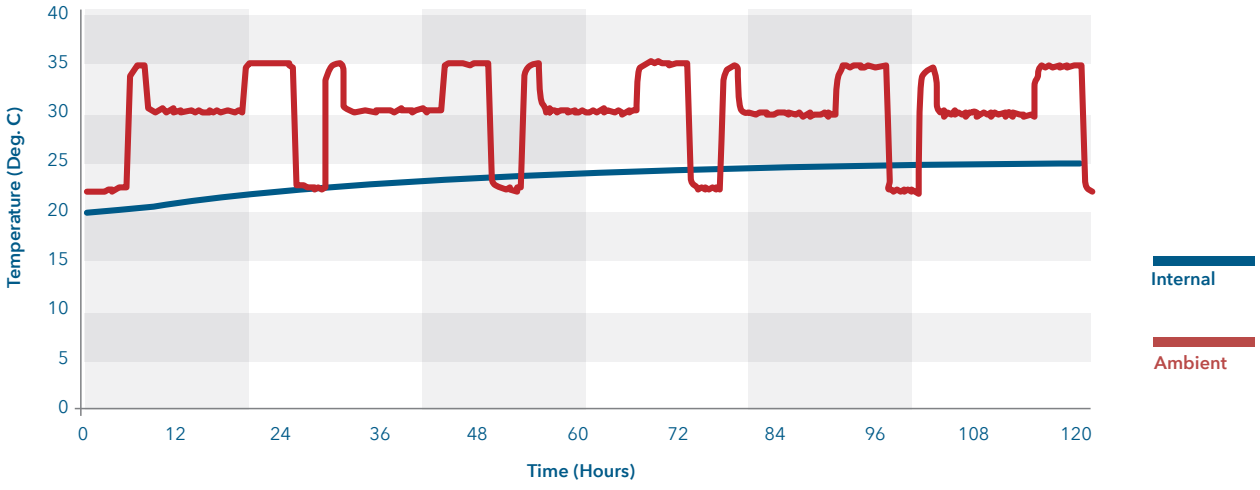
Note: True universal conditioning will only work with bracketed CRT systems that contain both temperature points in their phase change material.

A universal CRT shipper system designed with a bracketed PCM coolant system is the best method to protect against both temperature excursions and cold shocks. A bracketed PCM solution with two variants of PCM, with differing, yet complementary phase points will protect the payload against hot and cold external temperatures on every shipment. This bracketed PCM system should use 16°C and 24°C PCM to create a simple 17°C to 23°C universal conditioning point, which is designed to be used in year-round ambient conditions. No need for special treatment, etc. This offers tight temperature control of the payload space and true universal conditioning and pack-out for controlled room temperature shipments.

Series 22 Universal - 24L, Unit 1, Thermal Performance

(ISTA 7D Summer Profile, 1ea 5mL Saline Filled Syringe Payload)

Source: Pelican BioThermal Lab, 20 December 2016



An example of thermal performance for a bracketed PCM CRT system, compared against an ISTA 7D summer profile.

FOR MORE INFORMATION ON CRT CHALLENGES,
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