



Prioritizing Patient Safety: Advancing Controlled Room Temperature (CRT) Medication Shipping

Prioritizing Patient Safety: Advancing Controlled Room Temperature (CRT) Medication Shipping (March 2024)

Presenter: Murthy Doddasomayajula, Thermal Engineer (murthyd@flymaxq.com)

Moderator: Car Cooper, Marketing Coordinator (carcooper@flymaxq.com)

Agenda

- Company
- Definition of Controlled Room Temperature (CRT)
- Risk of Traditional CRT designs
- Precision Engineered CRT Solution
- Seasonal and Regional Challenges to CRT Systems
- Key Takeaways
- Q & A

Who Are We?



- Largest, innovative blood packaging solutions provider
- Serve 1100+ hospital blood banks and blood centers globally
- We help safely deliver 20,000 blood products per day, 23M blood samples per year, 1,000's of sensitive medications direct-to-patient
- Expansive technology portfolio



GRIFOLS

Eliminate product loss. Enhance regulatory compliance.

Deliver sustainable cost savings. Increase efficiency.



CERUS



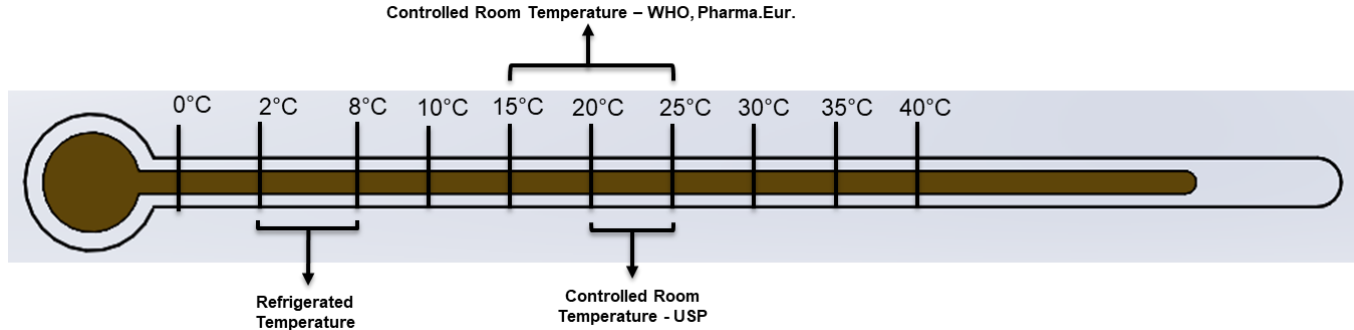
MaxPlus PharmaPack™ SP

- Pre-qualified, high performance packaging solutions
 - ✓ Purpose designed to deliver consistent product temperatures
 - ✓ Low DIM weight – reduced shipping costs
 - ✓ Simple, easy to pack
 - ✓ Easy to meet URAC requirements
 - ✓ Full PQ testing support
- Multiple sizes, temperatures (Ref, CRT and Frozen), up to 96 hours
- Medically integrated dispensing, Health System Specialty, Direct to patient/provider



Definition of Controlled Room Temperature (CRT)

- Temperature range for CRT can vary depending on the regulatory body.
- According to USP, CRT is defined as 20-25°C (68-77°F).
 - Excursions between 15°C - 30°C (59°F - 86°F) is allowed, provided the mean kinetic temperature does not exceed 25°C
- According to WHO and Pharma.Eur, CRT is 15 - 25°C.
- For this webinar we will consider, CRT to be defined as 15 - 25°C (59°F - 77°F).

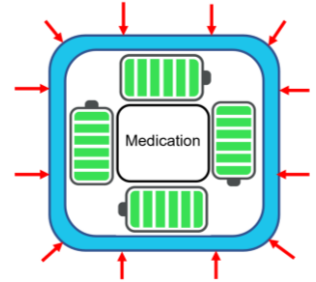


CRT is not easy...

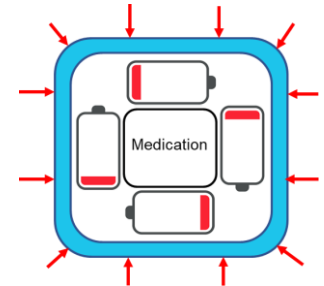
- The Texas Board of Pharmacy found “**80% of the packages shipped in the study reached temperatures deemed “Excessive” or “Unsafe” by the FDA and the USP.**”
- A Study by Utah College of Pharmacy, concluded that “**Current shipping methods used by mail-order pharmacies expose the contents of unrefrigerated packages to potentially unsafe temperatures.**”
- The study found that up a packages could spend up to **43%** and **15%** of shipping duration outside the required temperature range in winter and summer.

Risk of Traditional CRT Designs

- Traditional CRT system → Water based gel packs + Styrofoam cooler.
- A phase change acts as a thermal battery inside the system
 - Maintains a specific temperature
 - Protects the payload from temperature excursions
- Insulation delays the impact of the ambient on the payload.
- Since water changes phase at 0°C, the water-based gel packs are usually conditioned inside a freezer to use them to ship refrigerated products.
- For CRT systems, water-based gel packs usually comes from room temperature (18-24°C).
- Since room temperature, water-based gel packs remain liquid and do not change phase, their contribution is very limited in CRT systems.



Refrigerated Shipment
with water based gel packs



CRT Shipment with water
based gel packs

Case Study

Customer: [Specialty Pharmacy A](#) with national distribution.

Issue: Multiple CRT drug shipments were lost to temperature excursion during the winter cycle in early February of 2024. All these are overnight priority shipments with less than 12 hours from pharmacy door to patient door.

Current packaging: Styrofoam cooler with water-based gel packs (seasonal pack-out)

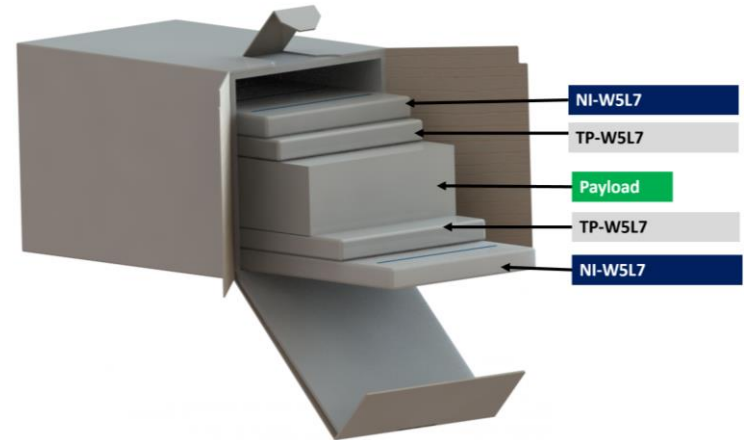
Solution: Precision engineered CRT design.

Precision Engineered CRT Design

Integration of dedicated phase change material

Design:

- ✓ Thermal performance goal: 24 hrs. of temperature hold time (summer and winter)
- ✓ Temperature: 15 to 25 °C
- ✓ Size: 10" X 8" X 8"
- ✓ Payload capacity: 1.5L.
- ✓ System weight under 5lbs.

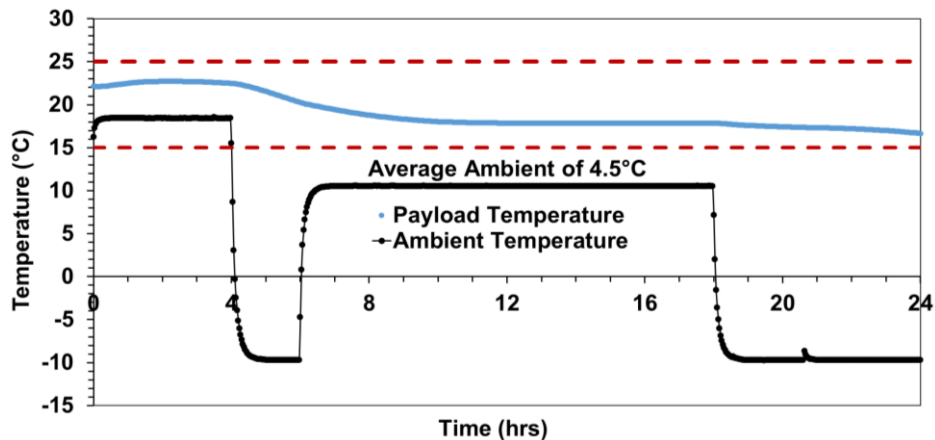
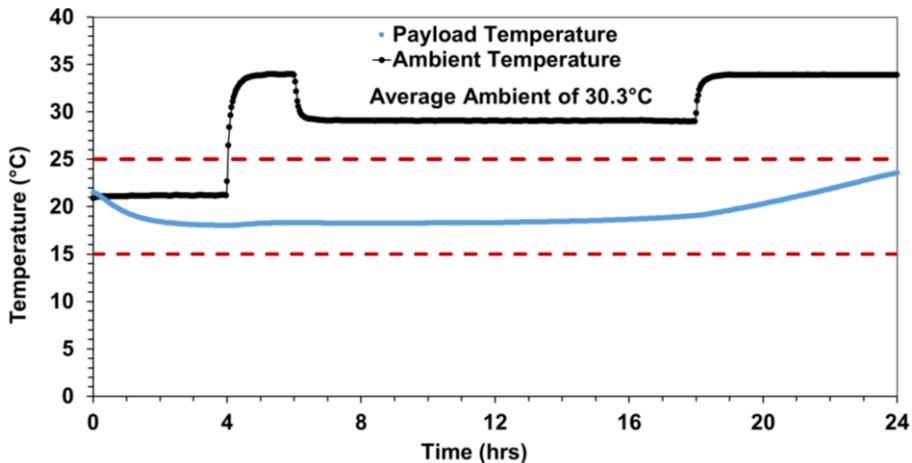


How did we do in lab testing?



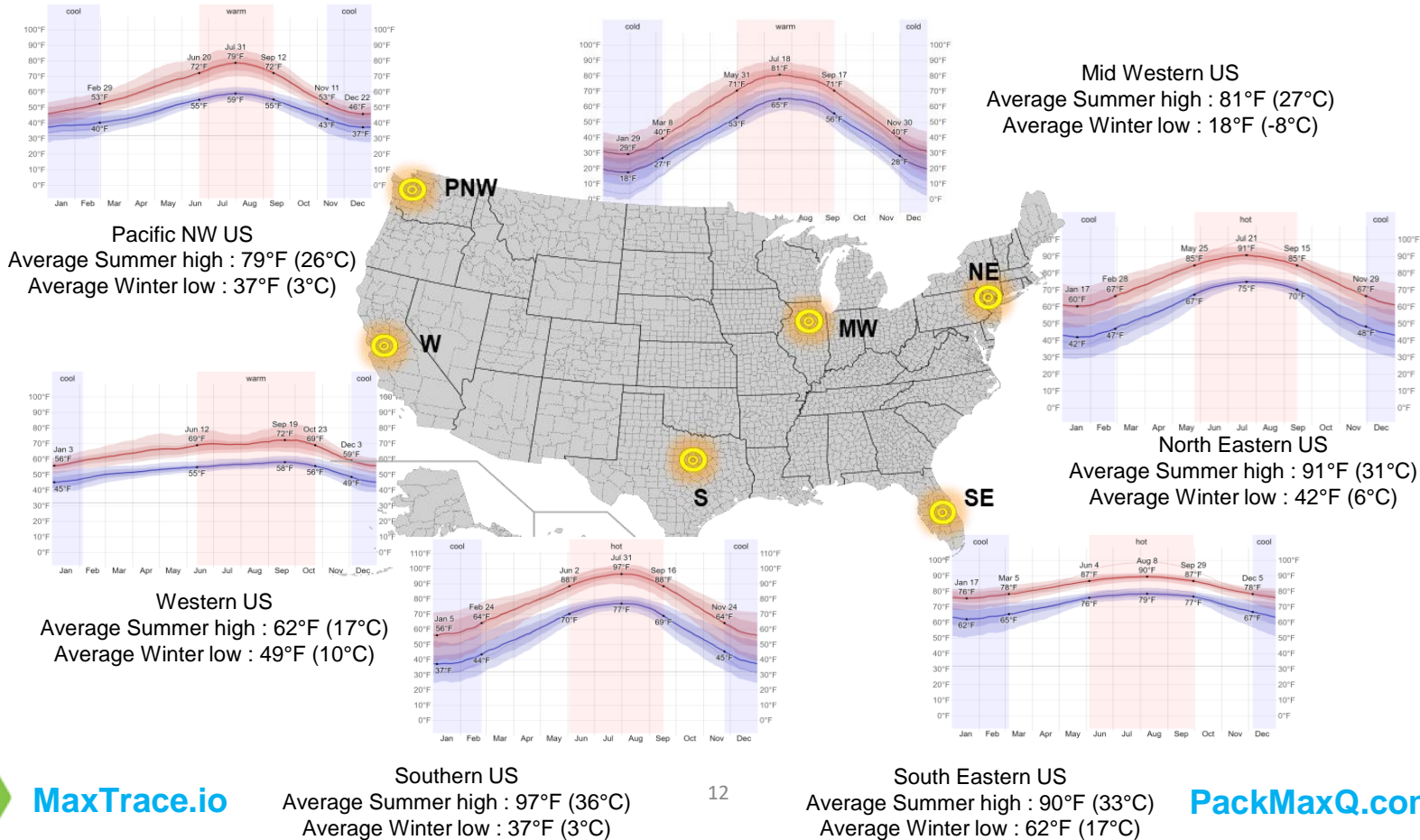
ISTA 7D Summer and Winter

24 hours of 15 – 25°C



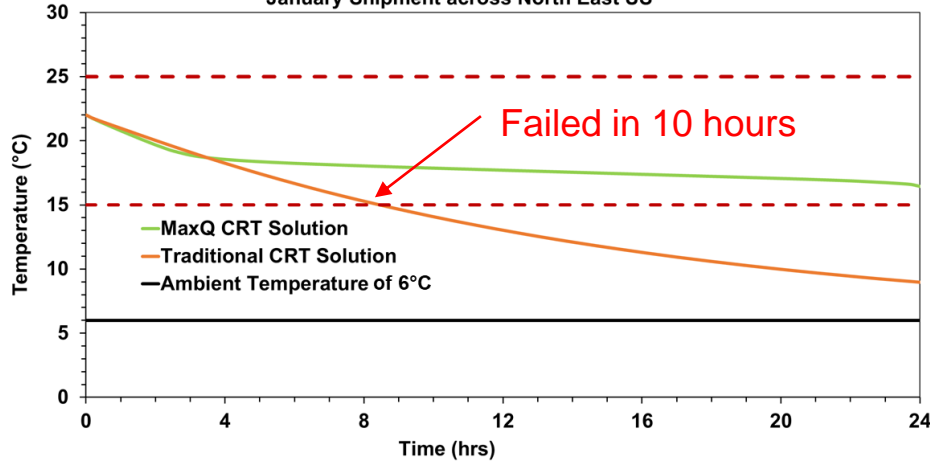
PQ Testing adds a whole new dimension
Especially when you ship across the country...

Seasonal and Regional Challenges to CRT Systems



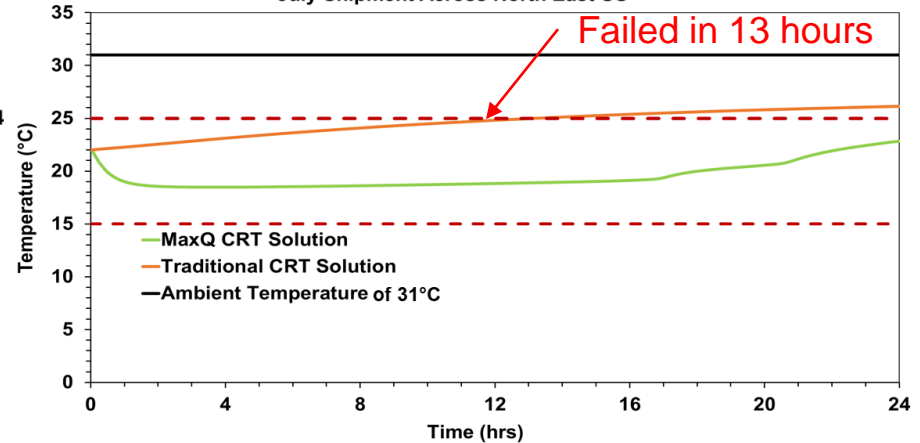
Comparison of CRT Systems – North East US

January Shipment across North East US

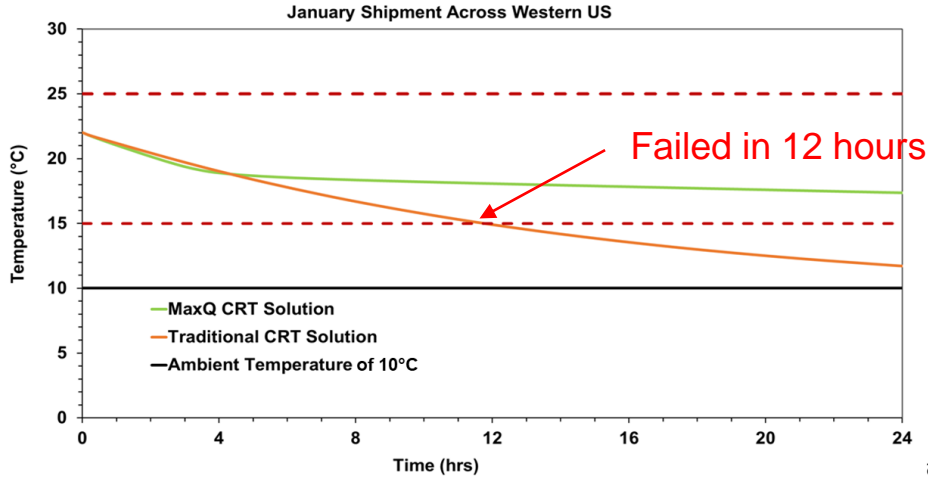


Comparison of traditional CRT and MaxQ solution's performance in North East US for months of Jan and July.

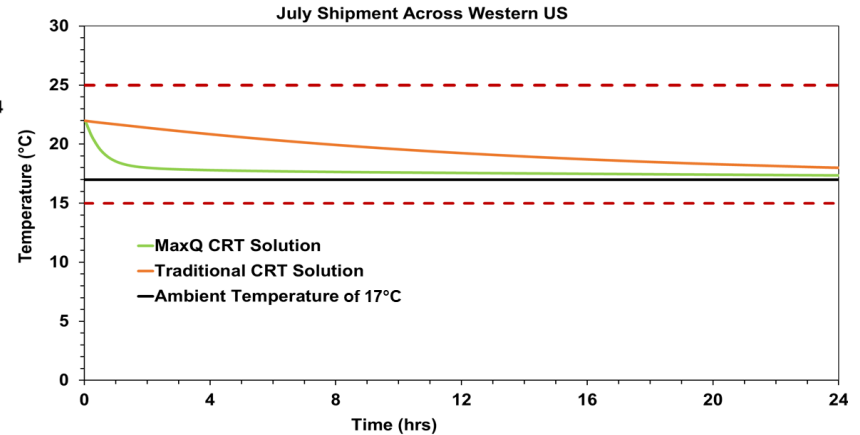
July Shipment Across North East US



Comparison of CRT Systems – Western US



Comparison of traditional CRT and MaxQ solution's performance in West US for months of Jan and July.



Key Takeaways

- Water-based systems work for refrigerated products but **fails to protect** CRT products during shipment, especially during winter cycles.
- Precision-engineered designs are necessary for mitigating the risk of temperature excursion in shipping CRT products.
- Such solutions ultimately ensure patient safety, provide confidence, and improve the experience in receiving mail-order medication from Specialty Pharmacies.

Happy Customer: Specialty Pharmacy A!



THANK YOU...

If you have questions or need assistance with your validation or qualification, e-mail us at support@flymaxq.com.

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