



Not all temperature controlled containers are equal when it comes to thermal performance – is your vital pharmaceutical shipment at risk?

Jonathan Neeld, Director of Certification & Regulatory Compliance at CSafe Global CFD modeling performed by David C. Weatherly, Ph.D., Weatherly Applied Research LLC

## SUMMARY

WAS DESIGNED WITH PERFORMANCE IN MIND

Although Active Temperature Controlled Containers (ATCC) for air cargo transport may rely on similar mechanical components to manage the heating and cooling of the cargo compartment, the interaction between these components and the physical design of the container make a significant difference in the operational performance of the active container system during shipment. This study shows the difference that airflow design and the recirculation pathway have on critical thermal mapping characteristics within an ATCC cargo compartment, and thus demonstrates that not all containers are created equal when it comes to thermal performance. CSafe relied on the results of this study to confirm that the design of its unique and innovative Air Recirculation System (ARS) technology used within the CSafe RKN would also function well for the new CSafe RAP container design. The CSafe RKN and CSafe RAP active containers transport vital pharmaceutical and biological products at the right temperature, with a very tight tolerance on set-point temperature, and the ARS technology goes a long way to ensure optimal performance of the containers.

# BACKGROUND

Active Temperature Controlled Containers (ATCC) are designed with the aim to maintain payload temperatures throughout all segments of the end-to-end transport. The World Health Organization's Good Distribution Practices states in section 13.4, "Pharmaceutical products should be stored and transported in accordance with procedures such that: the identity of the product is not lost, the product does not contaminate and is not contaminated by other products, adequate precautions are taken against spillage, breakage, misappropriation and theft, appropriate environmental conditions are maintained, e.g. using cold chain for thermolabile products."

In order to comply with these GDP guidelines, most ATCC's rely on six integral mechanical systems that aim to maintain an internal temperature set-point: 1) control system, 2) refrigeration system (condenser, compressor, and evaporator), 3) heating system, 4) airflow system, 5) internal energy source and 6) thermal insulation. These different components work together to maintain the desired air temperature within the cargo area, while counteracting the effects of ambient temperature outside the ATCC.

The key to uniform temperature mapping within the cargo compartment is the ability for the airflow system to autonomously regulate the cargo temperature. The airflow system relies on input from the control system, and multiple temperature sensors strategically placed within the cargo compartment to convey real time temperature data feedback to ensure accuracy and efficiency of the ATCC.

Figures 1 and 2.

CSafe RAP's unique and innovative
Air Recirculation System (ARS),
shown in Figure 1, and the
Temperature Management System
(TMS) with multiple sensors, shown
in Figure 2, autonomously work
together to envelop the payload
with conditioned air on all six sides
of the payload.





During the recent development of the new CSafe RAP, the importance of the interaction between the air recirculation design and the control of the temperature management system was found to be more critical with the significantly larger compartment volume of an RAP. To ensure that the design of the container could withstand the effects of extreme ambient temperatures, the CSafe engineering group used the latest Computational Fluid Dynamics (CFD) software to model various physical container designs to select the ideal airflow solution for optimal thermal performance of the container.

# MODEL DEVELOPMENT

To highlight the importance of air circulation within the cargo compartment and its direct effect on the temperature mapping of the payload, the CSafe engineering group analyzed three different airflow system designs to determine the most optimal configuration for the new CSafe RAP. The RAP container profile was used for all analyses as maintaining temperature across a larger volume is the worst-case scenario. Cross-sectional images of the three design models used in these analyses are seen in Figures 3a, 3b, and 3c. For simplification, only the cargo compartment of the containers is pictured with a minimum cargo configuration.

## Figure 3a.

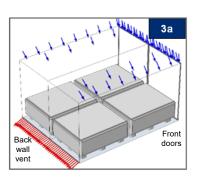
Model A (ceiling perimeter model with rear air return) forces air through ceiling plenum and out of small ceiling openings into the container.

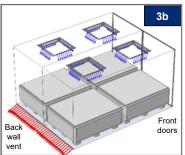
### Figure 3b.

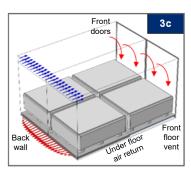
Model B (ceiling pods model with rear air return) uses 4 larger ceiling fans spread symmetrically across the top of the cargo compartment to push air around payload.

### Figure 3a.

Model C (rear forced air output with under floor return) pulls conditioned air around all sides of the payload and under the floor to circulate air throughout the entire container.







The CFD software used was COMSOL Multiphysics 5.3 and all analyses were conducted by Weatherly Applied Research.

### Ceiling perimeter model with rear air return (Model A)

In Model A, fans are used to push conditioned air from behind the rear cargo wall into a ceiling plenum that uses positive pressure to channel the air through multiple ceiling openings into the cargo compartment. The recirculation of the compartment air is then collected at an inlet opening at the base of the back cold wall with negative pressure (vacuum) from the fans behind the wall.

### Ceiling pods model with rear air return (Model B)

In Model B, fans push conditioned air from four distribution vents located in the ceiling to direct air, under positive pressure, into the cargo compartment. The recirculation of the compartment air is collected at an inlet opening at the base of the back cold wall, with the negative pressure (vacuum) from the fans.

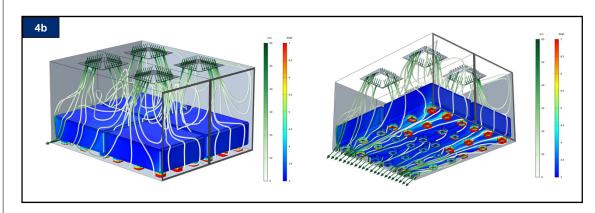
### Rear forced air input with under floor return (Model C)

Model C uses fans to push conditioned air from an opening in the top of the back cold wall, across both ceiling and side wall channels, to direct conditioned air throughout the entire cargo compartment. The recirculated air is then pulled through an inlet opening in the floor at the base of the cargo compartment doors by the negative pressure (vacuum) from the fans. The conditioned air is then channeled under the floor in a dedicated return air plenum to the rear of the container, where the recirculation cycle is then repeated.

# CFD MODEL RESULTS

The CSafe engineering group discovered that the interaction between the airflow system and the physical container design made a significant difference in temperature mapping results, and ultimately the overall performance of the ATCC. It was concluded that not all ATCC's are created equally, and system limitations, or airflow design differences, have the potential to put payload integrity at risk due to hot or cold zones developing within the cargo compartment.

Each of the three container models were analyzed based on two container payload configurations that simulate minimum and maximum load conditions. In this specific white paper, the focus is on the minimum load conditions understood by the industry to be the worst-case transport condition. In each of the figure sets below, there are two scales of measurement. The direction and velocity of airflow within the cargo compartment is illustrated by the ribbons shown in a gradient color scale from Dark Green (high velocity) to White (low velocity). The surface temperature of the payload within the cargo compartment is illustrated in a color gradient scale from Red (highest temperature) to Blue (coldest temperature).



# Figure 4a. Model A.

Insufficient airflow with slower air velocity around and under the payload indicates a significant elevation in temperature for the payload at the floor level. Also, airflow direction shows the streams circumventing away from the floor towards the return vent at the rear of the cargo compartment. Major temperature elevation can be seen at the interface between the pallet feet and floor indicating a higher risk for temperature excursion along the

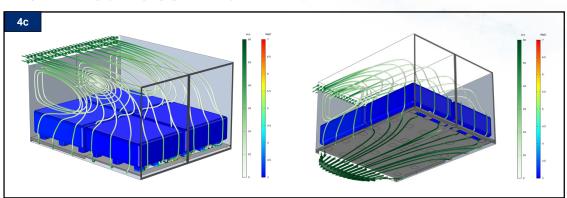
### Figure 4b. Model B

Again, insufficient airflow velocity, as indicated by the white ribbons, shows significant elevation in temperature at the payload floor level. Increased product temperature is shown at floor level for the two pallets closest to the door, due to low airflow and thermal shorting associated with the door seals. Major temperature elevation can be seen at the interface between the pallet feet and floor towards the front of the container. This would indicate the highest risk to the payload is at the front base of the container.

## Figure 4c. Model C.

This model shows consistent temperature mapping across the payload. With the vacuum vent placed in the front floor of the cargo compartment, conditioned air completely encapsulates the payload on all six sides. This figure demonstrates the consistent "air cushion" created by returning high velocity, conditioned air under the floor in the return channel.

## CFD RESULTS CONTINUED



The CFD model analyses demonstrate that Model C, with its dedicated return air channel under the floor, is the only container that generates consistent and higher velocity airflow patterns under and around all sides of the payload within the cargo compartment. This encapsulation of the payload with controlled, conditioned air results in excellent temperature mapping throughout the entire payload compartment, and thus removes the need for pallet utilization when loading the payload in the container. In the case of Model A and Model B, the CFD analyses showed that the reduction in airflow velocity and air distribution around the payload, with no dedicated return air channel under the floor, negatively impacted the temperature mapping inside the cargo compartment, especially at floor level under and along the sides of the payload.

# CONCLUSION

Based on the CFD analyses conducted in this study, airflow pathways and air velocity have a direct correlation with consistent thermal mapping within the cargo compartment. A faster airflow, together with a design that allows a complete encapsulation of the payload with conditioned air, will result in the most uniform thermal mapping across the payload, with optimal maintenance of the desired temperature set-point.

CSafe leveraged the results of this and earlier studies to expand upon the design of its unique Air Recirculation System (ARS) technology, incorporated in the proven CSafe RKN, to optimize the CSafe RAP airflow pathway design, mirroring Model C. The CSafe RAP's air inlet and return vents are located at diagonally opposing corners of the payload compartment, resulting in optimum circular airflow within the cargo area. The return air pulled under the floor through the dedicated return channel creates an additional insulating air barrier under the payload to further protect against the extreme ambient conditions encountered during Summer and Winter shipments.

In conclusion, all Active Temperature Controlled Container designs are not created equal and the CSafe range of active containers utilizes and incorporates innovative and differentiated designs to ensure optimal system performance and thermal protection of vital life-enhancing payloads.

# REFERENCES

WHO Guidelines for good distribution practices for pharmaceutical products. Geneva, World Health Organization, 2010 WHO Technical Report Series, No. 957. (Annex 5).

### Jonathan Neeld Bio Review

Jonathan is the Director of Certification & Regulatory Compliance at CSafe Global. With more than 25 years of expertise in the Design and Certification of Aviation products, Jonathan specializes in the development, certification and regulatory compliance of CSafe's active range of temperature controlled containers.

## David Weatherly Bio Review

David is a mechanical engineer with 20 years' experience in product research and development. He specializes in fluid dynamics and heat/mass transfer simulation (Computational Fluid Dynamics). David earned an M.A. in Computational & Applied Mathematics at UCLA and a Ph.D. in Mechanical Engineering (CFD) at University of Kentucky. After 14 years with the Inkjet Printhead Development organization at Lexmark International, he joined the University of Kentucky to do industrial research as an Assistant Research Professor. He now provides engineering research and product development services through his company, Weatherly Applied Research. He has carried out projects for The Timken Bearing Company, PPG Automotive Coatings Division, Kateeva, Inc., GE Electric Appliances and Lighting, and Kaleidoscope, Inc.

### Publications include:

- "Ejector Design for Delivery of Medical Aerosol to the Lungs", D. C. Weatherly, poster at Lexmark Research & Technology Symposium, 11/2011.
- "A General Model for Transition in Wall-Bounded Compressible Flows", D. C.
   Weatherly, presented at 4<sup>th</sup> International Symposium on Engineering Turbulence Modeling and Measurements, Corsica, France, May 1999.
- "Additive Turbulent Decomposition with Algebraic Map Turbulence Models for Compressible Flow", Ph.D. thesis, University of Kentucky, 1998.
- "Generation of Initial and Boundary Conditions for Large-Eddy Simulations of Wall-Bounded Flows", D. C. Weatherly and J. M. McDonough, poster at Eleventh Symposium on Turbulent Shear Flows, Institut Nationale Polytechnique, Grenoble, France, September 1997.
- "Computed Large-Scale Compressible Boundary Layer Structure Stimulated by Vortical Perturbations", D. C. Weatherly and J. M. McDonough, AIAA Paper 96-0424, presented at 34<sup>th</sup> Annual AIAA Aerospace Sciences Meeting, Reno, January 1996.