



## The AcuTemp® RKN by CSafe Achieves Operational Milestone and Approved Qualification Status from Major Pharmaceutical Companies



Three years of operational excellence plus independent extensive testing confirms the superior performance of the CSafe container in meeting the challenges of temperature control, even under extreme conditions.

The Operational Qualification (OQ) process employed for qualifying an active cooling and heating container along with the performance merits of the CSafe RKN were highlighted at IQPC's Cold Chain Distribution for Pharmaceuticals conference where pharmaceutical industry professional Geoffrey Glauser, Director Global Packaging Technology for Pfizer, presented an Operational Qualification (OQ) test

approach for active containers. As reported by Mr. Glauser, the AcuTemp RKN by CSafe maintained "exceptionally stable interior payload temperatures" when exposed to high and low ambient temperature extremes. Test results for summer and winter temperature profiles concluded the unit as "accepted for global shipping of drug substance and drug product with minimum and maximum mass/volume."

**The AcuTemp RKN by CSafe remains the only electrical heating and cooling container design approved by both European (EASA) and US (FAA) aviation authorities. Brian Kohr, President of CSafe, explains the story behind the company's drive to offer better solutions for the healthcare logistics sector.**



"CSafe is a joint venture between AcuTemp Thermal Systems and AmSafe, Inc. and is based in Dayton, Ohio, USA. AcuTemp is already a leading provider of temperature controlled packaging solutions and has an extensive range of products from prequalified passive boxes to other sizes of active systems. With the experience

we have gained over many years dealing with the specific requirements of the pharmaceutical and biotech sector, it was a natural phase of our development to produce the world's best performing electrical heating and cooling RKN container. Since it began service in 2008, the AcuTemp RKN has been used by over 60 pharmaceutical companies and has consistently demonstrated its ability to maintain a customer-desired payload set-point, in thousands of shipments. Due to the container's performance, the costs and environmental challenges associated with the use of dry ice, refrigerated trucking and internal packaging are all eliminated. Our customers have been telling us about the

need for a longer hold time, even without power, and so we developed our unit to have over 40% greater capability than competitive units — holding for over 100 hours in an ambient condition greater than 15 degrees from the set-point and maintaining that set-point in very extreme conditions, down to -30°C up to +49°C. This, together with the ease of use and immediate data download capability, drives the value of the CSafe solution much higher.

But I know that the superior technical capabilities of our electrical RKN are not the only important aspects of end-to-end temperature assurance. Our fleet continues to expand and with it so does the availability of the container on a global scale. We have carefully developed operating relationships with more than 20 major airlines who now accept the AcuTemp RKN for carriage on their aircraft. We will continue to extend these relationships to include an even wider range of professional supply chain partners who have the same passion for temperature assurance in the pharmaceutical and biotech sectors as CSafe."



“The CSafe RKN offers a reliable, temperature-controlled solution with the most innovative technology available in cold chain logistics. One of the many features is the immediate shipment temperature history data download from the RKN using a USB stick. Whether by air, road or sea, the CSafe RKN guarantees temperature data right on time.” Valerie Rowlands, Director Business Development, Europe, Middle East and Africa.

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We know from our research that the temperature-sensitive pharma and biotech industry were looking for alternatives and a trusted turnkey solution primarily in the 2°C to 8°C and 15°C to 25°C market segment. Customers now demand data logging and easier-to-use, qualified containers as an everyday offering. The design and thermal performance of the AcuTemp RKN by CSafe meets these needs and allows shippers and transportation companies to be more flexible in their logistics planning and reduce the need for hard-to-manage, costly, dry-ice and/or passive pallet shipping systems.

CSafe has developed a program that compares the cost of a company's current passive shipping program to the AcuTemp RKN active container solution. We want to help customers to improve the quality of their cold chain shipments, reduce or eliminate temperature excursions, and support their green initiatives while at the same time realizing significant cost savings.

Although the challenge of providing qualified solutions that meet the needs of manufacturers remains the top priority, there is

undoubtedly an increasing focus upon cost. Global growth of outsourced contract manufacturing has also created consistent trade lanes and CSafe has recognised this by providing flexible lease options that can reduce costs and allow for increased container utilization. This feature of our product offering, together with the proven capabilities of the container, has already established itself to be a successful combination. CSafe has also recognized the need for excellent technical and customer service. Our skilled team is always on hand to address specific customer needs and travels extensively to ensure that our customers receive the right level of training and support.

CSafe LLC is introducing an Enhanced Qualified User Program (EQUIP™) for users of CSafe's AcuTemp RKN, the cold chain industry's leading actively powered unit load device (ULD) used in the air transportation of temperature sensitive cargo. EQUIP accreditation was developed by CSafe to enable organizations and users of the AcuTemp RKN to realize the benefits of its innovative temperature management capabilities and to be better equipped to preserve the integrity of cold chain shipments. EQUIP accreditation gives our cold chain partners the tools and knowledge to take advantage of the RKN's superior performance and innovative features. The ultimate goal is to give RKN users the ability to confidently and effectively manage the challenges of today's complex cold chain shipping process.



From one extreme to the other,  
**CSafe™ can do what dry ice can't.**

Both heat and cool.

The AcuTemp® RKN from CSafe will keep your shipment at a precise temperature regardless of the climate and has the ability to heat and cool in order to maintain the required environment. From initial pick up in Helsinki to drop off in Buenos Aires, the AcuTemp RKN provides data logging throughout its journey. And it's the only FAA and EASA approved unit of its kind.



Visit [www.CSafeLLC.com](http://www.CSafeLLC.com) to learn more.

