



CSafe Service Center, Basel

Maintenance of any mechanical system is paramount to ensure optimal and consistent operational performance and service life of the equipment. At CSafe Global, we embrace this philosophy and made a commitment from day one of launching our active RKN container fleet that we would have the best maintenance program in the industry.

Prior to launching our Active RKN container, we heard concerns about the inconsistency in the performance of the existing container designs and how important it was that units, old and new, provided comparable performance. Stories from life science companies indicated that they were experiencing over 30% difference in the performance and direct outcomes of older units when compared to newer containers. This difference in performance becomes problematic for the quality and validation departments who have to make difficult justification for the continued use of older containers, as the original qualification testing was performed on newer containers. Several life science companies have smartly, in fact, implemented policies of accepting only containers of a certain age (i.e. only a certain container serial number or higher would be accepted). This burden is not something we wanted to place on our customers.

Therefore, it was critical to ensure that an active container that has been out in service for over 10 years would perform as well as a brand new container just

released from our factory. To maintain an optimum level of performance and reliability, CSafe developed a stringent maintenance program that is performed by our factory trained technicians at strategic global service centers.

The maintenance program has two components; "Scheduled Maintenance" and "Preventative Maintenance Rebuilds".

Scheduled Maintenance is performed on the containers at a predetermined period based upon a calendar interval or operational hours. For example, though the batteries have a manufacturer specified life of ten years, they are replaced on each container every three years. Scheduled maintenance also includes annual Temperature Validation and correlation of the container's temperature management system and data logging functionalities.

Preventative Maintenance Rebuild (PMR) program was developed by CSafe following the same principles and practices developed within the aviation industry where reliability and safety are paramount. These processes are not mandated by the regulatory bodies for this product, but CSafe has adopted this approach to ensure operational performance and reliability of the container for our customers.

The PMR process ensures we closely monitor every container in the fleet on a three year cycle and systematically identify and rectify any potential issues before they transpire. This approach is essential considering the delicate nature of the product being transported inside the containers.



The effectiveness of the Scheduled and PMR maintenance is very evident when you compare temperature validation data taken from RKN serial number 10 from early 2010 (approximately three years in service) and late 2015 (approximately nine years in service).

**The PMR process consists of the following steps:**

- Disassembly of the unit.
- Visual inspection.
- Verification of installations attachment & security.
- Functional testing of major components and systems.
- Scheduled replacement of certain components.
- Rebuild of the unit.
- Performance testing and temperature validation.
- QA final inspection & release.

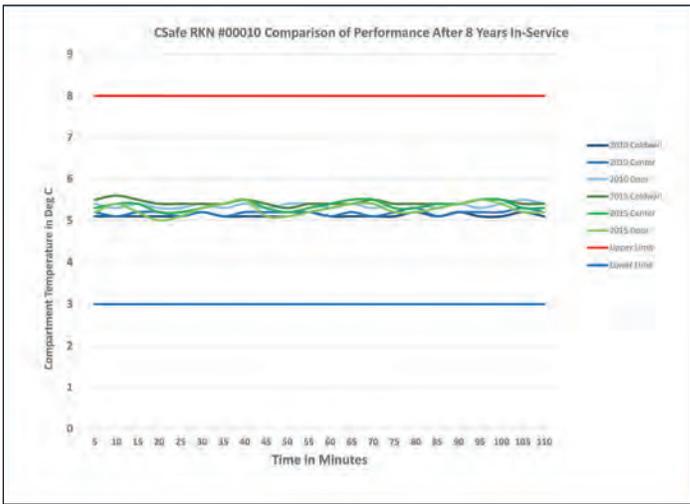


FIGURE 1



CSafe Unit #10 maintained and monitored for peak performance

The graph (FIGURE 1) shows the temperature readings at three set locations inside the container’s empty cargo compartment. The data clearly shows that the set point temperature of +5°C was maintained with a 0.5°C tolerance at all locations in both cases. The operational performance of the container has not degraded over the total in-service duration of nearly nine years. This maintenance approach also ensures consistent operational performance of any aged container across the entire fleet. An example is a recent seven container shipment that utilized containers ranging in serial numbers from 89 to 553. The set-point temperature for the product was +20°C. The international shipment took five days with an ambient temperature range of +14°C to +36°C.

The data and findings of the PMR are logged in the life history file for each RKN serial number within the CSafe asset tracking data base system. This allows the tracking and trend analysis of the findings. This data is used to identify additional preventative maintenance or future product enhancements for the fleet.

The information illustrates (FIGURE 2) the minimum and maximum temperature data captured over the five day period on each of the containers:

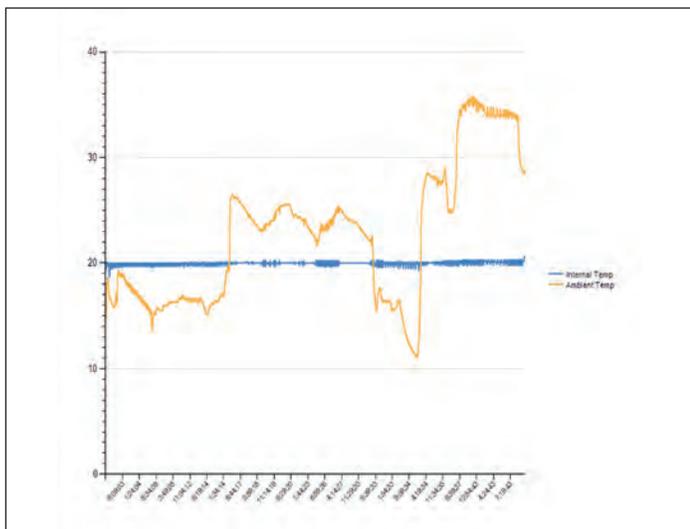
Description	RKN 00089	RKN 00096	RKN 00103	RKN 00173	RKN 00327	RKN 00374	RKN 00553
Max Temp during shipment	+20.2°C	+20.1°C	+20.2°C	+20.4°C	+20.3°C	+20.2°C	+20.2°C
Min Temp during Shipment	+19.7°C	+19.6°C	+19.6°C	+19.6°C	+19.7°C	+19.6°C	+19.6°C
Delta in Temperature	0.5°C	0.5°C	0.6°C	0.8°C	0.6°C	0.6°C	0.6°C
Lowest Battery level	76%	77%	78%	81%	79%	79%	80%

FIGURE 2

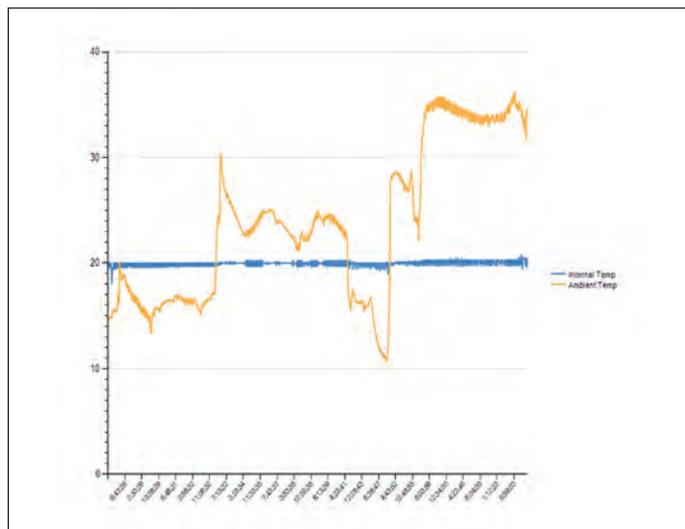
The data shows the consistency of the operational performance of all the containers over the five day shipment with no degradation in performance relative to age of the containers which ranged from two years old to seven years old.

The images (FIGURE 3) are two graphical examples of the shipment taken from the oldest RKN 00089 and from the newer RKN 00553 utilized in this shipment. The temperature management of the product temperature was identical.

Undoubtedly, this two phase approach to maintenance has been very effective and consistently protected our customers' high-value products over the past nine years. By adopting a proactive and preventative approach to the maintenance of our container fleet, along with the support of our global service center partners, we are able to sustain our industry leading performance both in quality and reliability irrespective of the age of the container being utilized.



**RKN 00089 Shipment Graph**



**RKN 00553 Shipment Graph**

FIGURE 3

#### About CSafe Global:

CSafe Global is the world's largest producer of actively controlled mobile refrigeration units for biopharmaceutical and healthcare companies, militaries, and international disaster relief agencies. CSafe Global brands include AcuTemp® passive packaging and hand-held mobile carriers, ThermoCor® vacuum insulation and the CSafe® brand of active containers.

The active solution product assortment includes the CSafe RKN, which utilizes heating and compressor-driven cooling technology to eliminate the risks associated with extreme ambient conditions [-30 to +49] as well as the cost, aggravation and environmental challenges associated with dry ice transportation. CSafe Global's AcuTemp brand has provided more than 10,000 hand-held mobile management solutions since its founding more than 25 years ago. The passive solution assortment includes packaging for 2-8°C, CRT and frozen shipments with hold times from 12 to 240 hours and with payload volumes up to 50 liters.