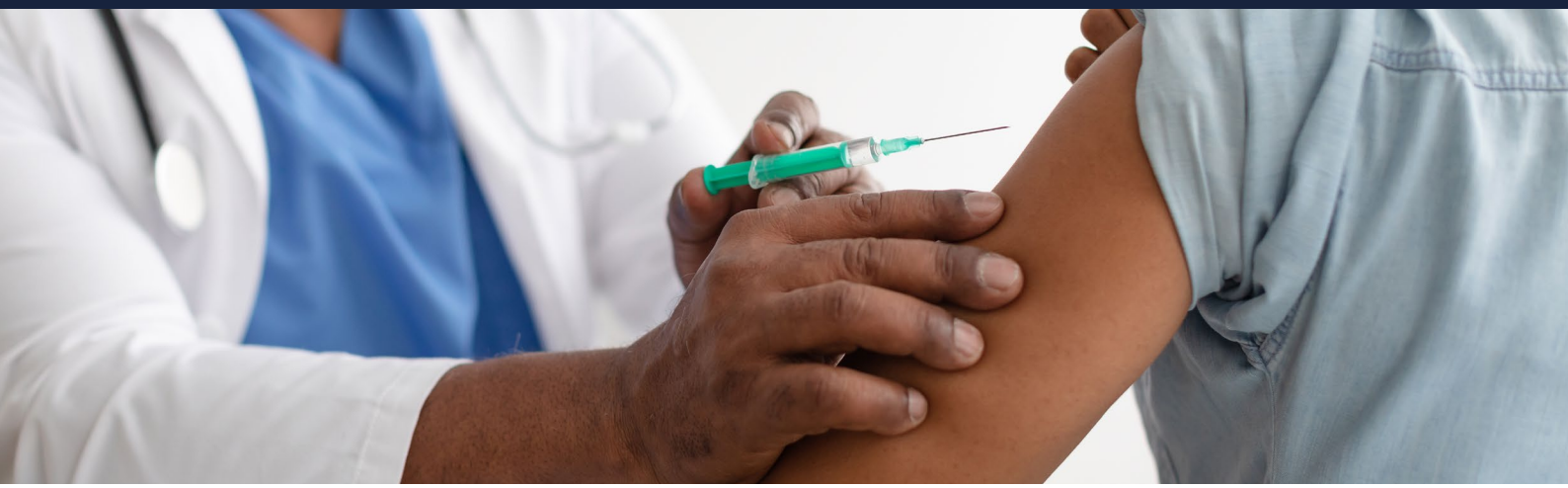

Shipment Visibility: Data Accuracy is Imperative for Success

In this second case study during our testing phase, we focus on the data accuracy during another round of pilot shipments.

Introduction

The ability to track and view cold chain medicine shipments, in real-time, has become a necessity for the pharmaceutical industry. Whether shipment tracking helps expedite drug acceptance upon delivery or prevents an excursion from happening in transit, the motivation for real-time shipment visibility remains the same – excellent patient care.

CSafe annually validates the ability of our Air Cargo fleet of containers to maintain and record accurate data. This temperature validation is important for pharmaceutical shippers to demonstrate compliance with FDA 21CFR Part 211.68a, the regulation for safe transportation of their pharmaceutical products. The data collected via the integrated tracking device and reported through the newly developed visibility platform, now adds additional information and redundancy to the validation dataset of the containers' shipment process, in real-time.

There are many aspects to review when selecting a tracking device. For CSafe, it was essential to choose a tracking device approved for flight on most commercial airlines, that could integrate directly into the system architecture of the Active Temperature Controlled Container (ATCC) and still transmit strong signal strength when installed. After extensive research and prototype testing, CSafe selected the Sendum PT300D.

Furthermore, the team understood that using or developing a custom visibility platform to be flexible, device-agnostic, and customizable for the cold chain user, would be critical for the project; CloudLeaf, Inc. met all needs.

The project development timeline is over half-way complete and CSafe's containers with integrated tracking devices have operated flawlessly on over 20 pilot shipments, with most moves including 6 container test-samples.

This case study uses the results of a completed pilot shipment to assess the accuracy of the data collected with the tracking device, in the new visibility platform, against shipment information collected directly by the containers' measurement systems. Until now, this container collected data was only available post-shipment, but with the integration of a realtime tracking device and a cloud-based platform to view the shipment, container data is available at any point during the lease.

Pilot Test Goals

CSafe's first shipment visibility case study covered the ability of the tracking devices to work within the containers and demonstrate which shipment parameters could be tracked, while this case study is written to determine the accuracy of the information collected.

Pilot 'A' shipments are only deemed successful if container readings, payload readings and pre-established alerts transmit in real time, during the shipment, and match the validated data the container is already logging.

Pilot Test Method

CSafe partnered with DHL Global Forwarding to complete these initial shipments and chose to test both RKN and RAP containers, loaded with actual drug product. The shipment reviewed in this case study features a non-stop international CSafe RAP shipment from Vienna, Austria to Chicago, Illinois recently completed on August 13, 2020.

City of Origin	Vienna, Austria
Destination	Chicago, IL
Modes of Transport Used	Road + Air

Table 1 - Pilot shipment transport details

Tracking software setup – All container tracking, alert and waypoint area configuration was setup in CSafe's new Visibility Platform.

Geofence location creation – Geofence locations and alerts established at start and end warehouse facilities, DHL hub facilities in Vienna and Chicago, and at the VIE and ORD airports.

Hardware configuration – All tracking devices configured with alert limits based on profile and allowable parameters for the product inside each container.

Results

Two containers – RAP 40355 and 40284 were picked up from CSafe's VIE service station on August 8, 2020. The Track & Trace development team tracked the containers as they traveled to the shipper's manufacturing site, the Vienna International Airport (VIE), went into flight-safe mode upon take-off, and when they were delivered at destination at Chicago O'Hare International Airport (ORD) before returning to CSafe's Chicago Service Center.

Image 1 - CSafe RAP

Both containers completed their shipment and lease on August 13, 2020. The data shown in this section come from RAP 40355 and the figures come directly from the Visibility Platform. CSafe tracked a variety of readings including location, payload and ambient temperature, shock readings, ambient compartment pressure.

On page 3, Figures 1 & 2 show the various data inputs being recorded with the shipment and Figures 3-5 illustrate the GPS views and highlight the precision of the map tracking.

Payload Temperature

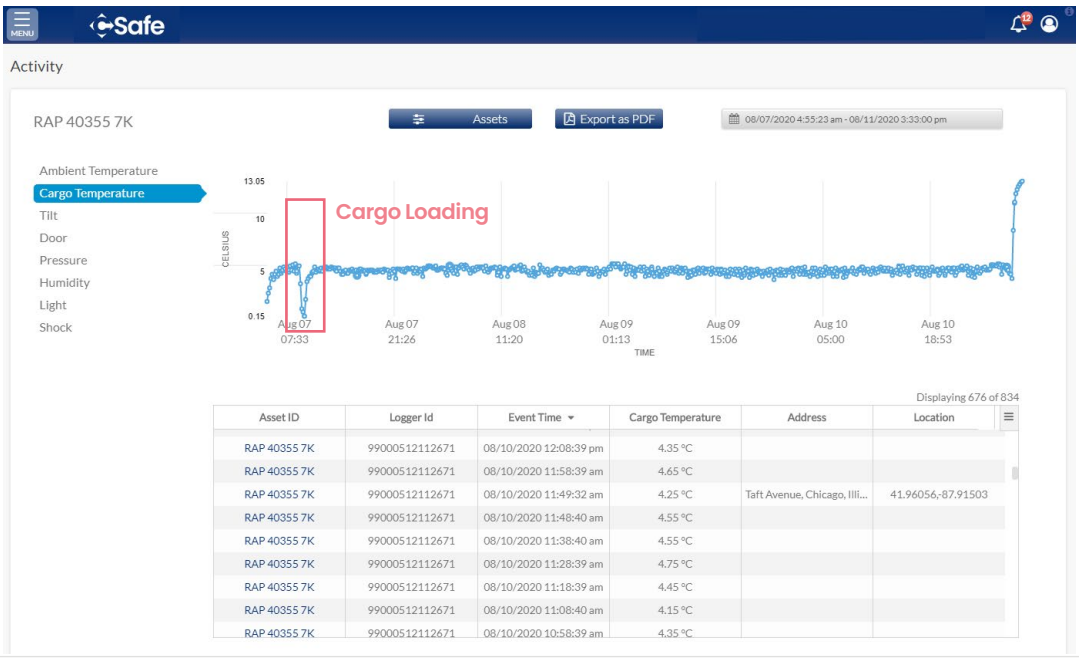

Figure 1 - Cargo payload temperature mapping, in real time.

Ambient Temperature

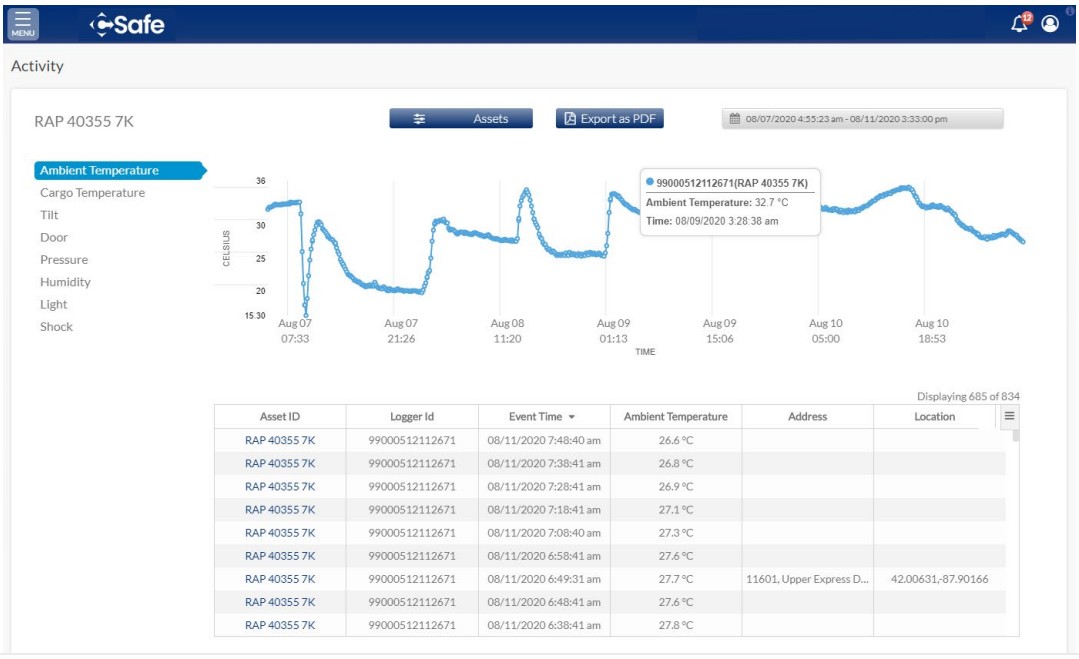

Figure 2 - Ambient temperature recordings, in real time.

GPS Location

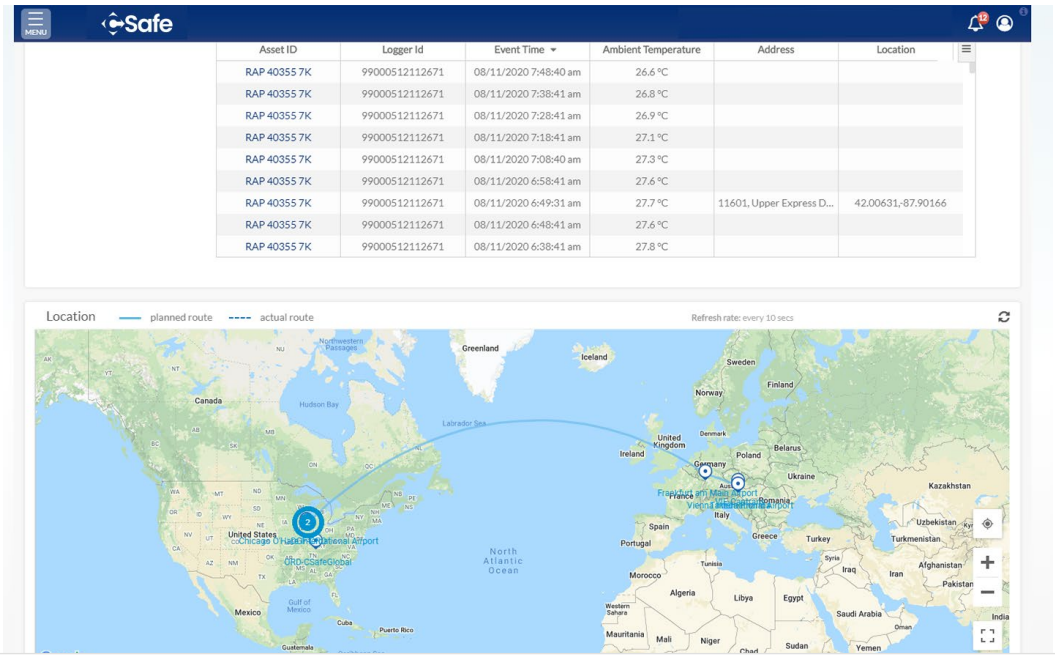

Figure 3 - GPS location mapping with historical route.

Cargo Temperature and Location

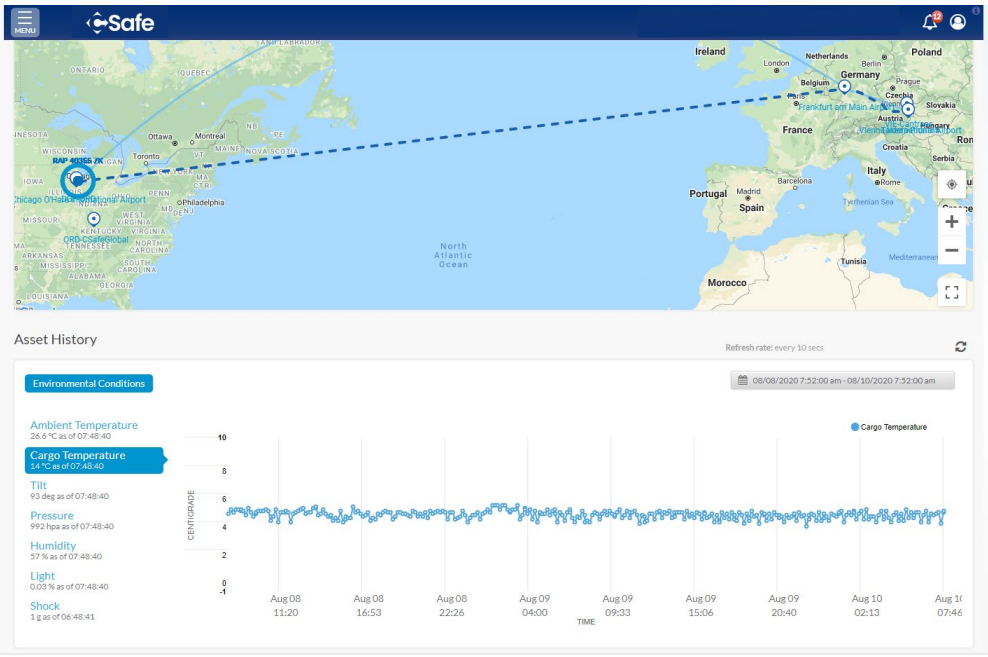

Figure 4 - GPS location mapping with historical route.

GPS Location on Arrival

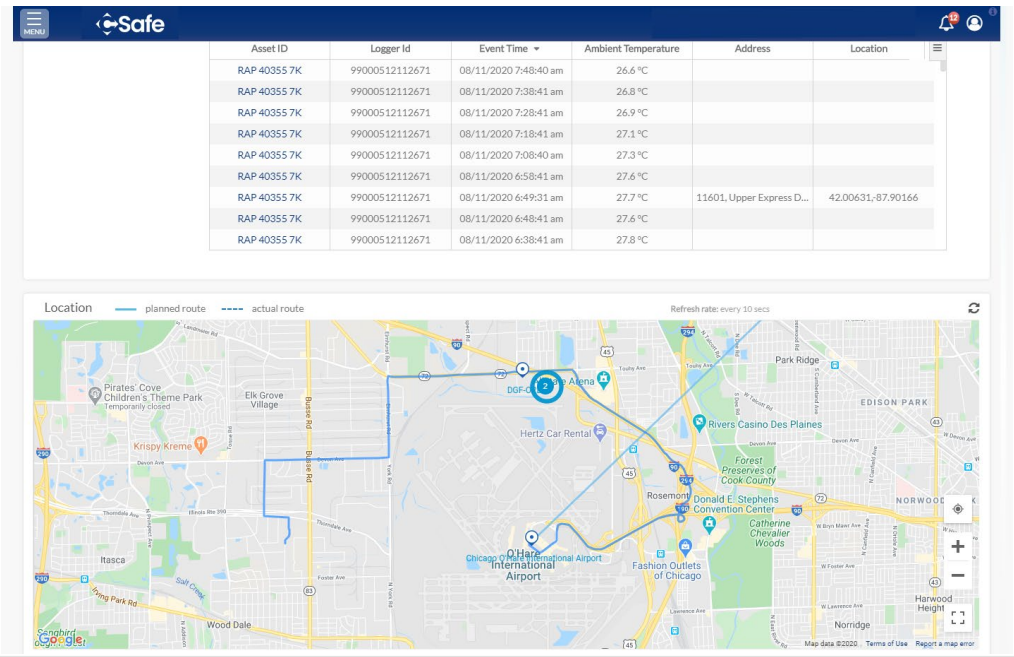

Figure 5 - Zoomed in view of GPS location upon arriving at destination.

Discussion

The graph below depicts the accuracy of the PT300D data when superimposed onto the container's log file data matches the data.

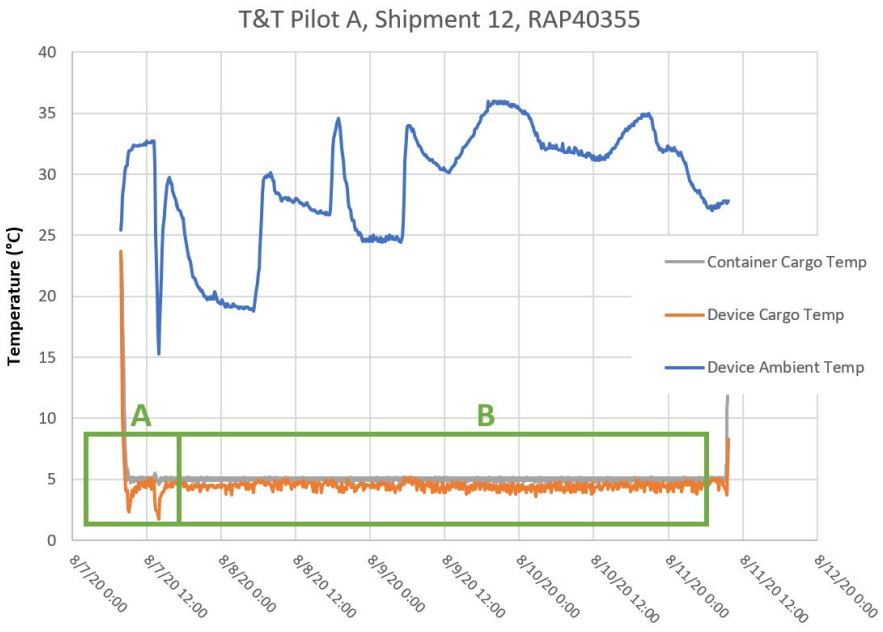

Figure 6 - Collected device data superimposed on container shipment log file. A and B labels reference discussion sections below.

Section A

The two small cargo temperature dips recorded by the PT300D device and illustrated in Figure 6 (pg.5), indicate the preconditioning and loading of the container. The first slight dip is the Sendum PT300D recording the first thermal undershoot, typical of preconditioning the chamber and happens before any product is loaded. The second dip corresponds to a door opening event when the payload was loaded against a high ambient temperature of 30°C. These events cause slight thermal fluctuations that the container averages between multiple temperature sensors within the cargo compartment. The duration of this event was around 45 minutes and indicates the RAP system is trying to maintain the air temperature to the selected 5°C setpoint and drives the temperature to the lower operating threshold of 2°C, to ensure the product is stabilized quickly once the doors are closed. These minor fluctuations are expected, have a rational explanation and are considered acceptable.

Section B

The cargo temperature averages from Figure 6 (pg.5), Section C are:

Start time	07Aug2020 @ 21:00 GMT
Stop time	11Aug2020 @ 06:00 GMT
Avg. PT300D recorded temperature	4.5°C (-0.9°C/+0.6°C)
Avg. Container recorded temperature	5.0°C (-0.3°C/+0.2°C)
Comparing device to container	PT300D was -0.5°C higher, on average

The CSafe RAP utilizes multiple thermistors, that are time-averaged, to control and maintain refrigeration operation. This same conditioned signal then gets recorded as the cargo temperature in the data log-file. Therefore, the internal temperature reported by the RAP results in a smoother signal. The PT300D utilizes an external probe, attached within the cargo compartment, to simply report internal cargo temperature at a set frequency and tends to look more jagged. The differences between the two are the result of an averaged signal meant for control versus a real-time signal meant for reporting.

Conclusion

In conclusion, the cargo temperature, as reported by the PT300D, matched the cargo temperature generated by the RAP's TMS, and was accessible throughout the entire duration of every container movement, granting the observer immediate insight regarding the status of each shipment. The accuracy and availability of this data advances CSafe's ongoing mission of ensuring the on-time delivery and proper temperature control of the life-enhancing products people need.

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