

DATA

Temperature from
-20°C freezers

INSIGHT

Defrost cycles were
erroneously occurring

ACTION

Replaced an incorrectly fulfilled
freezer with the appropriate model

Faulty Equipment Jeopardizes Integrity of Clinical Trial Materials

Background

The Company uses the Elemental Machines Connected Platform for monitoring its cold storage and lab environments. A -20°C freezer was used to house invaluable samples sourced from a multinational pharmaceutical partner. These thermally sensitive, irreplaceable, biological samples were used in global Phase 3 clinical trials for the company's coagulator. The company installed the Elemental Machines platform to monitor cold storage conditions in order to maintain the integrity of the clinical trial materials. Element-T units (temperature sensors) were installed in calibrated refrigerators and freezers, and Element-A units were installed to measure ambient temperatures in critical operating environments.

Problem

Soon after installation, the Operations Director noticed an unusual temperature profile for a -20°C lab freezer, as collected by the Element-T sensor. The freezer temperature displayed a cyclical spike about every 12 hours (see Figures 2a and 2b).

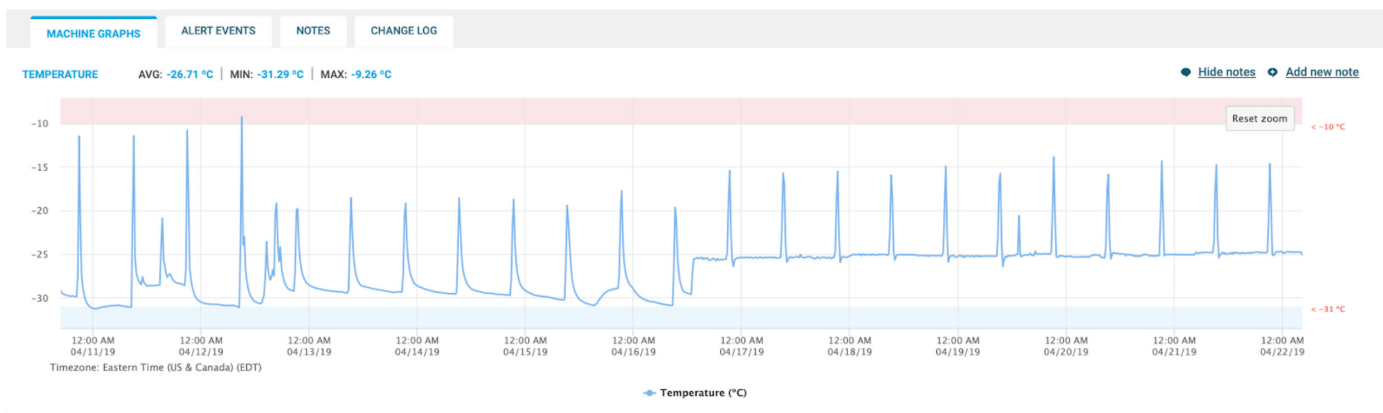


Figure 2a - Temperature profile of -20°C freezer displaying regular temperature spikes.

During these spikes, the temperature inside the freezer rose about 15-20°C above the setpoint, often triggering a temperature threshold alert. See Figure 2b for details.

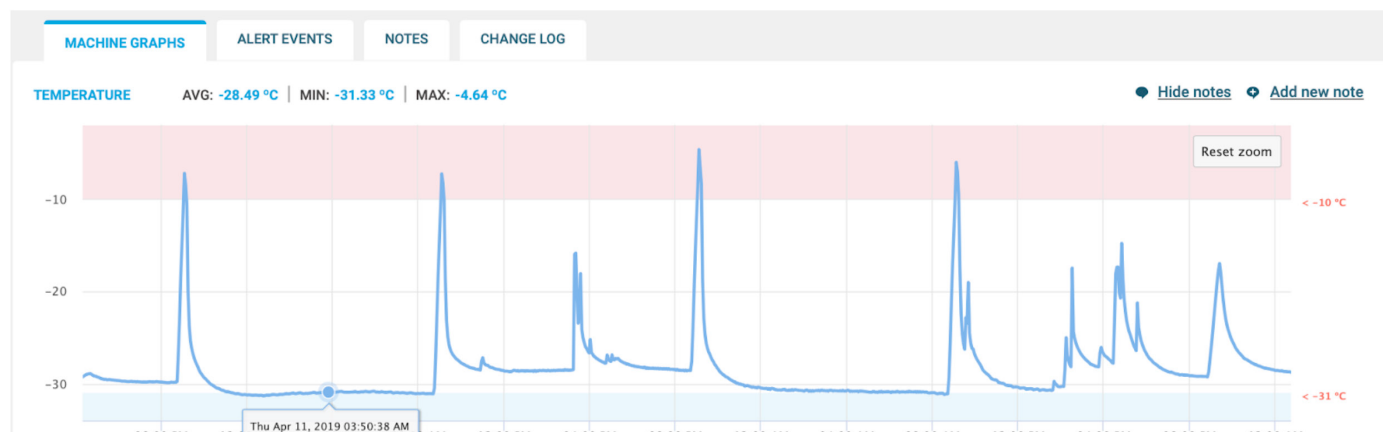


Figure 2b - Closeup of temperature profile of -20°C freezer in 2a showing that temperatures rose high enough to trigger alarms.

Within a couple of days, the team realized that the cyclical temperature spikes were not related to people actually opening the freezers and concluded the behavior was attributed to freezer performance. The spikes occurred even when no one was on-site, such as weekend and evening hours. To further confound the problem, the freezer display reported a steady temperature of -20°C, in contrast to the Element-T reading that regularly recorded temperature spikes. Had the team not had a backup temperature monitoring system they would never have known about this problem.

Solution

The team suspected that the temperature spikes may be the result of auto-defrosting cycles even though the company purchased a freezer model that the distributor believed did not have this feature. When the Operations Director contacted the distributor, the distributor again confirmed the model that the company was using did not have auto-defrost. However, when the company shared the Element-T data with the distributor, the distributor concluded that the freezer that was delivered and installed was indeed auto-defrosting and provided the company with a replacement unit of the correct model. The Element-T was installed in the replacement unit provided by the distributor. As can be seen in Figure 3, the replacement unit did not exhibit cyclical spikes like the previous freezer. While there are some minor spikes, Elemental Machines AI-model has characterized these as open door events. Their irregularity signifies that they are not representative of the defrosting patterns observed on the previous freezer.

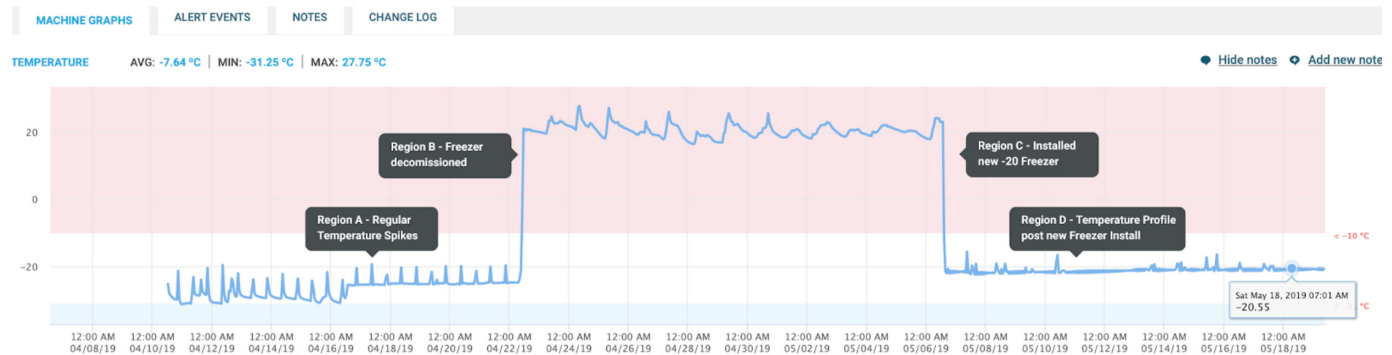


Figure 3: Temperature profile for -20 freezer. Cyclical spikes (Region A) indicate auto-defrosting. Temperature shift from freezing to room temperature (Region B) indicates freezer decommissioning. Temperature shift from room temperature to freezing (Region C) shows installation of new freezer. Temperature profile post new freezer installation (Region D) shows a much more stable temperature profile in comparison to the original freezer.

Results

Within two weeks of deploying the Elemental Machines Connected Platform, the company detected an equipment anomaly. Within four weeks, the company had a replacement freezer unit from the manufacturer. Data collected from the Elemental Machines Platform enabled the company to substantiate the anomaly to the freezer manufacturer. Had the team relied solely on the steady (and faulty) equipment reading, the anomaly may have gone undetected and likely would have compromised the integrity of the valuable freezer contents. Fortunately, the company team relied on the Elemental Machines Platform not only for comprehensive monitoring of its laboratory equipment but also for detecting equipment issues. The medical device company team continues to use the Elemental Machines Connected Platform for lab monitoring and independent verification of environmental parameters.

“ The Elemental Machines platform saved us from exposing our invaluable clinical trial samples to unacceptable storage conditions. These samples were collected during a large international Phase 3 drug program and are irreplaceable. We were lucky to have implemented the platform before transferring the samples, and plan to use the platform throughout our labs as we continue to grow. ”

Sasha
CEO