Guide to Cold Storage Monitoring

EVERYTHING YOU NEED TO KNOW ABOUT COLD STORAGE MONITORING - WHETHER YOU ARE JUST GETTING STARTED OR LOOKING TO OPTIMIZE YOUR SMART LAB APPROACH

ELEMENTAL MACHINES

Content

Chapter 1

The Current State of Cold Storage Monitoring

Cold storage monitoring is more than just recording temperature on a regular basis. Time-to-market, budgetary spending, and revenue generation are key metrics for many organizations. There is significant variability among lab professionals when it comes to how they measure and use freezer and refrigerator information.

Counterintuitively, only 25% of lab managers monitor all of their equipment, while 64% monitor some pieces of equipment, according to a survey conducted by Elemental Machines. This is quite shocking when one considers that 71% of lab managers have experienced catastrophic equipment failure that resulted in loss of critical samples or materials. The survey also revealed that refrigerators and freezers are the most commonly tracked equipment with 90% of lab managers have a monitoring system in place. The sad reality is that data management strategies in laboratory environments are inconsistent and many lack an integrated approach to managing, storing, and using data.

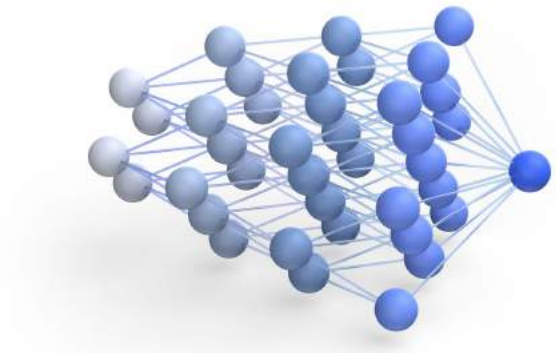
Moving to a data-first monitoring approach

Data-driven strategies have been used to optimize manufacturing of numerous types of products, from automotive to computer science. Likewise, moving towards an integrated, data-first approach has the potential to transform science-based industries. There is ample evidence that many scientific businesses are moving in this direction, but it can be challenging to know where to start when the vast range of possible solutions can be overwhelming.

It can be helpful to think about your organization's long-term goals and make short-term decisions that align with those goals. For example, if you're considering a monitoring solution -- either for the first time, or to replace a legacy system -- make sure one of your key evaluation criteria is seamless data exchange between your monitoring system and other systems of record. Any system that puts the burden on staff to manually move data from one system to another isn't helping move forward.

Monitoring: a springboard to the smart lab of the future

While the data show that monitoring is widespread, it's time to begin thinking of cold storage monitoring as a pathway to the smart lab of the future, rather than a goal unto itself. With that view, teams can begin to think about how data provided by monitoring systems can be used to accelerate their work.



Chapter 2

What is Cold Storage Monitoring?

Cold storage monitoring involves the use of thermostats and sensors to detect and collect the temperature (an other important conditions) of a closed systems such as refrigerators and freezers. More technologically advanced systems can send the data to a centralized platform that can be viewed by the end-user. This process is essential to protect the precious materials within, regardless of industry or application.

In many cases, it can be hard to put a value on samples stored in refrigerators or freezers because they are often irreplaceable. Furthermore, improper storage conditions for reagents may result in denaturation and ultimately failed experiments.

Because of the high stakes involved, freezer and refrigerator monitoring and alerting may be a valuable tool for those responsible for cold storage materials.
Not only does this provide peace of mind to teams, it is also required by regulatory agencies as crucial evidence supporting the scientific and experimental integrity of claims made. In the life sciences and pharma space, this is to protect the patients that will ultimately receive treatments and cures. Federal regulations such as 21 CFR Part 11 require proper and comprehensive documentation of cold storage temperatures. On the otherhand, in the agricultural space, it is to protect consumers against potentially harmful foods. To ensure foods have not been spoiled, the Food Safety Modernization Act (FSMA) also requires cold storage temperature monitoring.

When it comes to cold storage monitoring technology, weigh your options

Several years ago there were limited options for cold storage monitoring and alerting beyond simple thermometers requiring a person to manually record data over time. Thanks to new technologies, practitioners now have more powerful options at their disposal. So what are the options?

Thermometers

Thermometers have been in use for hundreds of years and represent the most straightforward method for monitoring freezer and refrigerator temperatures. Typically, a laboratory technician or other designated person visits each freezer or fridge at least twice per day and records the temperature reading from a thermometer monitoring the internal temperature. These readings are recorded in a log and can be stored for record keeping. Furthermore, the records are just that, a data log and cannot be used to make real-time adjustments or modifications.

While it is easy and straightforward to read a thermometer and record the temperature, there are some other issues that might make this technique less desirable. The initial capital cost of a thermometer is very low, but don't ignore the cost of paying people to read and record thermometer information every single day. If you have several cold storage facilities, it could take several hours per day for someone to make all these recordings. That can translate into relatively high operating costs.

In addition, while it's possible to keep records by storing the log sheets, this technique is also the most susceptible to

human error. Are all your thermometers positioned in a way that they can be easily read? Is lighting sufficient in all areas to be able to see the thermometer clearly? Manual recordings are also easy to tamper with in the case of a regulatory or liability action.

Chart Recorders

Chart recorders are another established method to keep a continuous record of freezer and refrigerator temperatures. They are reliable, fairly inexpensive, and easy to use. The charts can be saved and filed away to keep a comprehensive record of temperature. For these reasons, chart recorders have found wide usage or monitoring cold storage. Just like thermometers, chart recorders provide only a record, and no real-time alerting or notifications.

However, chart recorders still require someone to change out the chart paper, usually on a daily or weekly basis, and to file away the chart for compliance. Also, because of the graphic nature of the recorded data, thee is poor granularity between readings. If you want to get more resolution into small temperature differentials you will need to use a bigger chart recorder.

Another thing to consider is operating cost. Charts and pens cost money and need to be replaced. If you have dozens of chart recorders, paper charts and replacement pens costs can really add up over time. It can also be cumbersome to find a place to store all the used charts. The FDA requires that vaccine makers, for example, keep a log of freezer temperatures for three years. That's more than 1000 charts that must be filed away and stored for each freezer.

Today, there are digital chart recorders available for purchase, but they come at a higher pricepoint and still require the transfer of data from internal memory to an external digital storage location.

Data Loggers

Data Loggers are devices that measure and store temperature readings electronically. They offer continuous monitoring of freezer/refrigerator temperatures and can alarm (not remotely) when temperatures are out of specification.

Data loggers are more expensive than manual thermometers, but they offer the advantages of continuous monitoring and storage of data. The data saved by a data logger can typically be downloaded and stored using a USB memory device, or they can be connected to a local area network. Data loggers store a lot of information that can be easily saved and retrieved for regulatory compliance. What data loggers typically aren't set up to do is to alarm users remotely for out of temperature conditions. And data is typically not available in the cloud for easy access.

Wireless IoT devices

The latest innovation in monitoring capabilities is wireless internet of things (IoT) devices that can collect data remotely and transmit the data to the cloud. While IoT technology comes at a somewhat higher initial investment, implementing IoT monitoring brings with it numerous benefits to end-users.

These devices are easy to set up with no wires or connections needed. All sensors are battery operated and seamlessly connect to the internet where personalized data is imported to a portal in the cloud. Online portals allow users to monitor equipment in real-time and to receive out of temperature alerts instantaneously via email or SMS alert. This setup eliminates uncertainty caused by human error, stores data for years, continuously monitors equipment, and alerts designated users for out of specification conditions. Data are securely stored in the cloud and can be easily accessed for regulatory compliance. Furthermore, users are also alerted to low battery conditions or connectivity issues, so no data gets lost.

Chapter 3

How To Pick a Cold Storage Monitoring Solution

Building a fully connected, automated lab of the future, while ambitious and productive, can also be a nuanced and complex process. But fear not, if you've already decided to take a data-first approach to operations, then you've won over half the battle already. Listed below are a number of considerations to take into account when evaluating solutions.

Reliability and flexibility

Critical to the success of any lab monitoring system is its usability. For any monitoring system to be remotely useful, data must be easy to access and readily available 24/7 to teams both on-site and to those working remotely. Preference should be given to products with intuitive designs and shared web-based dashboards that enable users to track the performance of critical instruments and equipment, to understand usage patterns to optimize operations, and to quickly identify potential issues that may arise.

For many labs, change is inevitable so flexibility is the key to success. Having the capacity to adapt quickly and easily to accommodate future projects is a necessary consideration for most end users. For this reason, equipment monitoring solutions should be scalable in terms of number of users and pieces of equipment.

Compliance

Regardless of which quality system a lab is required to follow, be it GLP, GMP, ISO or CFR QSR, adopting a laboratory monitoring system will facilitate meeting the requirements for detailed, thorough record keeping. Capturing time-stamped electronic data of test parameters will increase the efficiency of the lab while eliminating the likelihood of human error.

Beyond compliance, captured data can be further utilized to drive process changes and optimize laboratory operations. For labs that fall under the jurisdiction of FDA compliance, 21 CFR Part 11 specifies requirements for electronic data collection and storage to ensure that the data collected is trustworthy, reliable, and equivalent to paper records as part of a complete audit trail. Events such as user logins and changes to key parameters that may affect process outcomes must be tracked.

For compliance purposes, lab monitoring systems must also include user management and data security features such that only authorized users may access the system, that data measurements are non-editable, and that event details are time-stamped to ensure data integrity.

Managed risk

Cost savings are often at the core of managing any laboratory budget. By utilizing a laboratory monitoring system, end users can avoid the time-consuming expense of facility walk-throughs and paper-based recording processes. Automated email and/or SMS alerts of instrument failures can prevent loss of valuable, and often irreplaceable, laboratory materials and specimens. Finally, equipment utilization data can offer insights on equipment usage patterns and influence purchasing decisions regarding capital expenditures.

Installation & maintenance

Wireless and battery operated monitoring devices offer easy installation solution for laboratory monitoring, and when equipped with low-battery warnings and cellular backups they offer 24/7 operation with full confidence that data will always be available.

Data Integrity

Lack of repeatability and reproducibility of results is a common problem for many researchers. The inability to confidently repeat protocols and achieve identical outcomes results in enormous amounts of wasted time for scientists and delays in research progress. Much of the problem surrounding irreproducibility of data lies in a lack of information and insights into how ambient conditions can influence experiments. Fortunately, advanced laboratory monitoring systems are a simple remedy to the problem.

By reviewing data for equipment status and ambient conditions (operational data), researchers are able to rapidly identify issues contributing to experimental variability and rule out those factors that are not actually affecting experimental results. Furthermore, researchers are able to refine protocols by specifying optimized environmental and instrument parameters to achieve the desired results.

An important consideration when it comes to operational data is sample rate, or how often information is gathered from the environment or equipment. Lab monitoring systems that provide higher granularity with a more frequent sample rate may be able to help teams decipher confounding results more easily than systems that sample less frequently.

Chapter 4

The Special Case of Cryo Tank Monitoring

Maintaining temperature of cryogenic storage tanks is vitally important to ensure that temperature-sensitive samples are not harmed. Cryo tanks are thermally insulated to maintain exceptionally low temperatures. Unlike refrigerators and freezers, cryo tanks require additional monitoring capabilities to measure not only temperature but also nitrogen and liquid levels within the tank itself. While temperature sensors and data loggers can be used to take measurements within the tank itself, however special sensors designed to measure liquid nitrogen may also be required to ensure proper functionality of the system. There have been many stories of valuable samples lost due to power outages or simple evaporation of liquid nitrogen. In many cases, cryo tank monitoring could have prevented these losses.

Chapter 5

Sustainability and Cold Storage Monitoring

Laboratories consume five to ten times as much energy as regular office space. A large majority of this energy consumption is a direct result of electricity, gas, steam and air conditioning that is required to maintain constant, precisely controlled environments, such as general lab workspaces, and cold storage units.

Sustainability in the lab begins with simple to implement practices – such as chilling ultra-low temperature freezers to -70° C instead of the traditional -80°C, which can reduce energy consumption of the freezer by up to 40%. It is estimated that the biotech and pharma industries could save as much as $1.25 billion annually by decreasing energy usage by 30%. But, in order to achieve these types of energy savings, organizations must first embrace cold storage monitoring practices to:

- Identify current operational temperatures of units
- Confirmation that changes to cold storage unit settings are achieved and maintained

While this may seem like an above and beyond action, the reality is that these types of initiatives will soon be required by regulatory agencies around the globe. Over 70 countries have set net-zero energy targets to reduce carbon emissions 45% by 2030 and reach net zero by 2050.

However, most biotech and pharma companies have not established targets that aligned with Net Zero initiatives. Starting with cold storage monitoring can be an easy place for organizations to begin working towards cutting carbon emissions and meeting sustainable regulations.

Chapter 6

The Future of Cold Storage Monitoring

The advent and maturation of artificial intelligence (AI), machine learning, and IoT has a growing presence in our lives. Imagine what we could achieve if we were to unleash the powers of these solutions for science and medicine.
Many strides have been made in remote monitoring and alerting capabilities through IoT-enabled devices that allow end users to monitor and receive alerts, should storage conditions deviate from specified settings.

The next iteration of this progression will leverage big data and data science to provide users with powerful insights based on actual operational data from the lab. For instance, with machine learning and AI, end users will be notified about predictive failure of equipment in the lab, based on the actual equipment performance over time and deviations throughout the lifecycle of the equipment. Sophisticated, yet simple solutions like this, can make all the difference when the stakes are high and the samples are irreplaceable.

Elemental Machines' Cold Storage Monitoring Solution

Elemental Machines' ecosystem of hardware and software is trusted by science and technology leaders around the world to help optimize operations and accelerate their pace of scientific innovation.

Always on

Your organization invests in assets to perform mission-critical functions aligned with your organization's objectives. Whether you are monitoring assets that Elemental Machines' solution is a reliable, 24/7 IoT-connected platform that helps teams efficiently monitor valuable assets and receive real-time alerts when systems are at risk.

Equipment monitoring

- Refrigerators
- Freezers
- Ultra-Low temperature freezers
- Cryogenic freezers
- Incubators
- Ovens

Facility monitoring

- Laboratories
- Manufacturing floors
- Vivariums
- Greenhouses
- Server Rooms

Customized alerts

Our robust rules engine allows you to customize alerts via SMS and/or email when your equipment or environment deviates from the norm, even during power outages. You can also automate your alerting workflow via escalating messaging so that the right people are notified at the right time.

Accessibility and traceability

The cloud-based Elemental Machines Dashboard gives you a bird's-eye view of your entire fleet of assets. When alerts are triggered due to non-conformances, your quality team can directly comment and annotate their corrective actions within the system for audit-friendly reporting.

Advanced analytics

Through continuous high-resolution measurement of your equipment, the Elemental Machines AI-powered platform learns the health of your fleet over time. Our data science engine uses advanced machine learning techniques to understand normal vs. abnormal equipment behavior to determine the impact of the environment fluctuation and ultilization on so that you can optimize equipment performance over its entire lifecycle.

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