ELEMENTAL MACHINES

Guide to Ambient Environment Monitoring

BACKGROUND

Monitoring of ambient environmental conditions, such as temperature, pressure, humidity and light levels, is a vital requirement for many industries and applications. Life science labs can have millions of dollars of equipment that can be negatively affected by changes in ambient conditions. Materials and chemical processing plants often run processes that are sensitive to environmental conditions. Changes in humidity or pressure can have detrimental effects on yield and quality. Food service, storage, and transportation companies must ensure foods are properly stored and transported according to standards outlined in the Food Safety Modernization Act (FSMA). Incubators used for culturing medical, bio and pharma should be constantly monitored to ensure optimal growth conditions are maintained.

INTRODUCTION

Regardless of what specific quality standards or regulations apply to your industry, a proper environmental monitoring program should be able to answer the following questions. Are my environmental monitoring devices accurate? Are we paying proper attention to our environment - monitoring regularly and taking some action when an out of spec condition occurs? Are we keeping sufficient records to ensure our product safety and quality? If regulations exist for our industry, are we keeping sufficient records to satisfy these regulatory requirements?

There are essentially five choices for monitoring ambient conditions:

- Manual thermometers, barometers, hygrometers and light meters.
- Chart recorders to record one or more parameter
- Data Loggers
- HVAC facility monitoring
- Wireless IoT devices

In this guide we will briefly describe each technique, how it's commonly used and what the advantages and disadvantages are of each technique.

ELEMENTAL MACHINES

THERMOMETERS, BAROMETERS, HYGROMETERS, LIGHT METERS

These individual devices have been in use for decades and represent the most straightforward method for monitoring ambient conditions. Typically a technician or other designated person visits each monitoring station at least twice per day and records the readings from the various instruments monitoring the environment. These readings are manually entered into a logbook and can be stored for record keeping.

While it is easy and straightforward to read these devices and record the temperature, humidity, pressure or light level, there are some other issues that might make this technique less desirable. The initial capital cost of these instruments is fairly low, but don't ignore the cost of paying people to read and record all this information every single day. If you are monitoring several environments, 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 instruments positioned in a way that they can be easily read? Is lighting sufficient in all areas to be able to see the instruments clearly? Manual recordings are also easy to tamper with in the case of a regulatory or liability action making them less reliable than other records.

PROS

- Low capital cost
- Simple
- Well established

CONS

- Higher labor cost
- No continuous monitoring
- Record keeping is cumbersome
- No real-time alarming
- Human error

PROS

- Continuous monitoring
- Data storage is straightforward
- Relatively simple

CONS

- Operating cost
- No real-time alarming and notification
- Record keeping is cumbersome
- Poor granularity of data

CHART RECORDERS

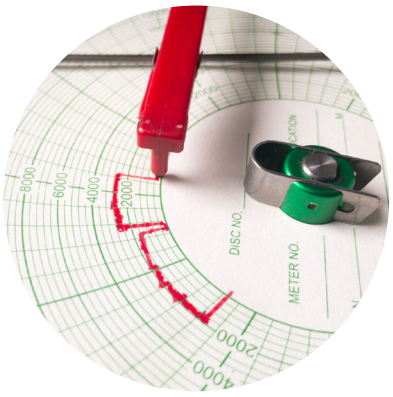

Chart recorders have been used for decades to keep a continuous record of various readings such as temperature, pressure and humidity. They are reliable, fairly inexpensive, and easy to use. The charts can be saved and filed away to keep a comprehensive record of ambient conditions. For these reasons chart recorders have found wide usage for monitoring various environmental factors.

While they are reliable and easy to use 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. If you want to get more resolution from your readings 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 the cost of paper charts and replacement pens can add up. It can also be cumbersome to find a place to store all the used charts.

DATA LOGGERS

PROS

- Continuous monitoring
- Data storage is straightforward
- Relatively simple

CONS

- No remote alarming and notification
- Data typically not available in the cloud

Data Loggers are devices that measure and store readings electronically. They offer continuous monitoring of various parameters. Some data loggers measure several parameters at once, such as temperature, pressure and humidity. Data loggers can be set up to alarm when readings are out of specification.

Data loggers can be more expensive than manual instruments, but they offer the advantages of continuous monitoring and storage of data. They can also be set up to alarm for out of range conditions. 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 spec conditions. They also are typically not set up to make data available in the cloud for easy access.

HVAC FACILITY MONITORING

Newer HVAC systems have many options for monitoring and control. Oftentimes these systems are used to look for problems with the HVAC system itself, such as chillers that might need maintenance before they fail. However, these systems can also be used to monitor and control specific environments within a building.

These systems can be used to monitor ambient conditions in critical areas such as food storage or vaccine storage for temperature, humidity, and light levels. HVAC facility monitoring systems often allow for remote control and monitoring of out of spec conditions through cloud-based interfaces.

PROS

- Continuous monitoring
- Data storage in the cloud
- Remote alerting

CONS

- Can be very expensive
- May only be feasible for new construction
- May not alert the right person

These systems are often pricey and may only be practical for new construction. Another downside for the researcher or lab manager is that the alarm system is often built for the facilities people and not for people running laboratories or doing the research, so an out of temperature alert is likely to get sent to a facilities manager rather than a lab manager. The facilities manager might not understand the criticality of the work being done in the environment that is being monitored and may not respond with the urgency required.

WIRELESS IOT MONITORING AND ALARMING

Wireless IoT monitoring is easy to set up with no wires or connections needed. All elements are battery operated and seamlessly connect to the internet and to a personalized data portal in the cloud. The portal allows the user 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 spec conditions. Data are securely stored in the cloud and can be easily accessed for regulatory compliance. Users are also alerted to low battery conditions or connectivity issues, so no data gets lost.

PROS

- Continuous monitoring
- Data is stored in the cloud
- Simple installation
- Remote alarming

CONS

- Somewhat higher initial costs

REGULATORY COMPLIANCE

There are numerous quality and regulatory standards across multiple industries requiring environmental monitoring, data storage, and alerting for out of spec conditions. Some of these standards include:

- FDA 21 CFR Part 11 compliance for electronic records to help ensure that electronic data collected is trustworthy, reliable, and equivalent to paper records
- The Food Safety Modernization Act (FSMA) requires that proper temperatures of food are maintained throughout the supply chain.
- The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) states that rooms that are considered critical, like those where invasive procedures are performed or where sterile items are stored, are to be in constant compliance when being used for their intended purpose.
- The World Health Organization (WHO) Technical Report Series No. 961, 2011, Annex 9 provides guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products, which requires monitoring and alarming for temperature and humidity.