ELPRO

WHITE PAPER

Losing Everything: Is a Chart Recorder Enough to Protect Critical Assets?

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Losing Everything: Is a Chart Recorder Enough to Protect Critical Assets?

Perhaps, unfortunately, this scenario is all too familiar: You arrive at work on Monday morning and hear an alarm sounding from your refrigerator. You walk over to your fridge to check the chart recorder and see abnormal spikes on the paper graph, but a detailed analysis by quality control personnel is required to take any action whatsoever. You find out that the chart doesn't show enough data for a quality-based decision, so the product inside has to be discarded. Panic sets in. The monetary value of the supplies pales in comparison to the fact that patients today are relying on the medicine inside. In the event of an excursion, do you know if your product is still acceptable? Or maybe you were performing a critical study and now may have lost days worth of time and data. This scenario is very real and very costly for many facilities – hospitals, pharmacies, food manufactures, pharmaceutical companies, biotech – the list goes on. However, the good news is that this is preventable!

How? An electronic monitoring solution that provides meaningful and analyzable data of environmental conditions. Do you monitor your critical environments? If so, what if your data is in the form of outdated charts or requires cumbersome data downloads and software applications? Perhaps you're new to regulatory scrutiny and your monitoring system does not exist yet. Outdated solutions, or even worse, no solution at all, is likely costing your operation time, revenue, and valuable data analysis capabilities; not to mention the risk of being non-compliant.

As you know, environmental monitoring plays a vital role in the manufacturing (cGMP) and healthcare (JCAHO) markets. cGMP's for a wide range of consumer and veterinary products are, in general, modeled from well-established pharmaceutical practices. Recent JCAHO regulations now require compliant monitoring and record keeping that includes traceable data of critical environments.

Portion of a timestamped minute-by-minute temperature report that can be generated from an electronic data logger.

	Date	Time	Sensor 1	Sensor 2	Info
101	03.07.2015	13:33:20	+29.9 °C	+40.0 %rF	
102	03.07.2015	13:34:20	+30.0 °C	+40.0 %rF	
103	03.07.2015	13:35:20	+30.1 °C	+40.0 %rF	
104	03.07.2015	13:36:20	+30.3 °C	+40.0 %rF	
105	03.07.2015	13:37:20	+30.3 °C	+40.0 %rF	
106	03.07.2015	13:38:20	+30.4 °C	+39.9 %rF	
107	03.07.2015	13:39:20	+30.6 °C	+39.7 %rF	
108	03.07.2015	13:40:20	+30.6 °C	+39.7 %rF	
109	03.07.2015	13:41:20	+30.7 °C	+39.1 %rF	
110	03.07.2015	13:42:20	+30.6 °C	+37.2 %rF	
111	03.07.2015	13:43:20	+30.6 °C	+36.8 %rF	
112	03.07.2015	13:44:20	+30.4 °C	+36.6 %rF	
113	03.07.2015	13:45:20	+30.4 °C	+36.3 %rF	

So although the details of best practices will vary by industry, a basic approach is applied when it comes to environmental monitoring: it's critical.

Paper-based records dominated regulated industries for years, and consequently environmental monitoring is still performed with paper-based chart recorders in many facilities with longstanding SOPs. Yet, chart recorder technology dates back to a century ago, and despite the fact that there are newer, high-tech alternatives, the chart recorder still lives on. If your facility currently uses chart recorders or if you have been presented with the chart recorder as your option for environmental monitoring, now is the time to consider an electronic method.

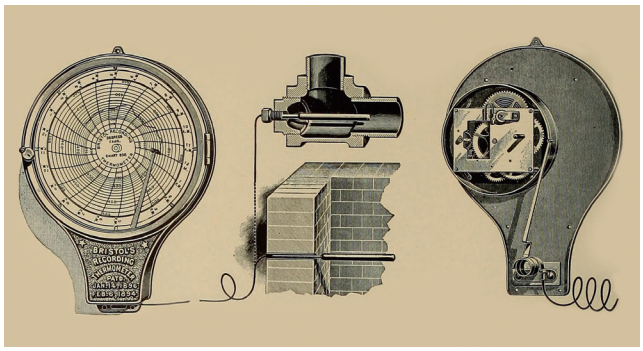
Electronic monitoring methods are superior technologies that can add significant value to your operation. Advantages of electronic monitoring far outweigh reasons to avoid making a change to SOPs. An evident advantage is the ability to switch from paper records to electronic records. Electronic records and reports allow for easier storage, quicker accessibility and safer backup of vital information, all at a lower cost.

Additionally, electronic monitoring technologies outperform chart recorders because they can provide meaningful, traceable data. Meaningful environmental monitoring data is time stamped, point-by-point recording of the exact environmental conditions that can be used to determine exactly how long an excursion lasted. You won't get this type of information from a chart recorder.

The Case Against Chart Recorders

The first chart recorders used for environmental monitoring date back to over 100 years ago in 1915. Known as strip chart recorders, circular chart recorders and roll chart recorders, these electromechanical devices require high maintenance and are highly subject to human error. **Table 1.1** provides an overview of the downsides, underlying costs and risks associated with using chart recorders. The critical downfall of the chart recorder is that it cannot record point-by-point readings, making an in-depth review of data inefficient and time consuming, delaying the decision-making process.

Utilizing a chart recorder is reactive in nature, whereas electronic technologies give real-time access to operating conditions and alarms. This allows administration to pro-actively address excursions and monitor trend data, potentially circumventing the loss of product or priceless research samples.



Temperature chart recorder from the early 1900's. The same design concept is used in chart recorders today. Photo credit: A History of Stevens Institute of Technology.

Your Research is Innovative, Why isn't Your Monitoring Method?

The FDA began encouraging cGMP's to implement electronic records and other modern manufacturing technologies in the early 2000's when the guidance «Pharmaceutical cGMP for the 21st Century» was issued. Although adopting a modern approach to quality and risk management is not mandatory, this FDA guidance encourages «modern and innovative manufacturing technologies», including «quality control measures, necessary data collection, monitoring and appropriate controls for the product and process».

The downsides, underlying costs and risks associated with using chart recorders (Table 1.1)

Downside	Underlying Costs / Risks
Change chart paper weekly	- Cost of paper charts - Staff hours needed to change paper - High risk to human handling errors
Stock chart paper	- Storage space dedicated to paper - Inventory of chart paper
Pen / ink cartridge replacement	- Cost of pens / cartridges - Possible downtime if pens / cartridges aren't in-stock - High risk to human handling errors
Mechanical / moving parts	- Repair / maintenance costs - High risk to human handling errors
Power supply	- Battery replacement or dedicated power outlets required to run
Written deviation reports	- Time of staffed personnel for written deviation reports - High risk to human handling errors
No built-in, backup memory	- Prone to data loss - Lack of redundancy
Filing / storage charts and reports	- Physical storage space dedicated to store charts and reports - Cost of staff hours for filing - High risk to human handling errors
Prone to sensor drift	- Expensive to calibrate - Accuracy / reliability

«Most importantly, chart recorders cannot record point-by-point readings, making an in-depth review of data inefficient and time consuming, delaying the decision making process.»

Most recently, «21st Century Cures», a 2015 US House of Representatives initiative, encourages the health science industries to embrace advances in technologies. The initiative was prompted from the recognized need to speed up vaccine approvals at both the regulatory and manufacturing level, prompting manufacturers to seek new, efficient methods to document product quality. The mission states, «… health research is moving quickly, but the federal drug and device approval apparatus is in many ways the relic of another era. We have dedicated scientists and bold leaders at agencies like the NIH and the FDA, but when our laws don't keep pace with innovation, we all lose.» Your research and products are innovative and your monitoring method should be, too.

Why is Temperature / Environmental Monitoring Critical?

Regardless of your industry, maintaining precise accuracy of environmental conditions is critical to the storage and testing of your products and samples.

- In the food industry, 1% difference in humidity creates a 1% difference in the weight of cheese, which creates a 5% profit loss for the company.
- Reliable, repeatable temperature and humidity tests determine the shelf life of a product.
- The viability of cell cultures and vaccines are dependent upon precisely controlled environmental conditions.
- Preventing a warehouse storage loss can equal millions of dollars saved.
- Contract laboratories, biobanks and other industry third-parties must prove that their clients' products are stored and tested properly.

Simply stated, monitoring is critical because temperature and other environmental conditions will affect the efficacy and purity of your products, samples and goods. Applying a modern approach to monitoring will not only provide the traceable evidence you need to have confidence in your product, but it enables you to prevent product loss by monitoring trend conditions, react to alarms and analyze data to determine whether samples were affected by any excursions.

An excursion can happen for a number of reasons. Obvious causes are system component failures and power outages. However, even routine procedures can lead to an alarm condition. Have you ever opened your refrigerator door at home only to find that it was not closed all the way? Maybe the door seal failed or the last person to use it didn't quite push hard enough to close the door, and nonetheless, you stand there and feel the warm air and wonder if the contents in the fridge have gone bad. How long was the door left open?

What if this happens at your lab, hospital, testing or manufacturing facility? Even many 24/7-staffed labs may only check equipment and rooms twice daily. System alarms can go unnoticed resulting in lost and damaged product. Do you know what happens at your facility on evenings or over the weekend? Can you check the status of your labs from the comfort of your home?

What Controlled Environments Should I Monitor?

- Ultra-low Freezers
- LN2 Tanks
- Freezers
- Refrigerators
- Patient Refrigerators
- Incubators
- Environmental / Stability Chambers
- Growth Chambers
- Cleanrooms
- Storage Rooms
- Warehouses

These are all examples of controlled environments that ultimately affect product characteristics and quality or are used to store expensive or irreplaceable product.

What you are required to monitor is highly dependent on your market and application. **Table 1.2** (next page) provides examples of common critical points used by industry.

Common critical points to monitor by industry (Table 1.2)

Industry	Monitoring Task	Critical Point(s)
GMP: Pharmaceutical, Food and Beverage, Cosmetic, Dietary Supplement, Veterinary Products	Refrigerator	Temperature
	Incubator	Temperature
	Freezer	Temperature
	Ultra-low Freezer	Temperature
	Environmental Chamber	Temperature, Humidity
	CO_2 Incubator	Temperature, Humidity, CO_2
	Cleanroom	Temperature, Differential Pressure
	Warehouse	Temperature, Humidity
Healthcare	Refrigerator	Temperature
	Patient Refrigerator	Temperature
	Freezer	Temperature
	Ultra-low Freezer	Temperature
University / College	Refrigerator	Temperature
	Freezer	Temperature
	Ultra-low Freezer	Temperature
	LN2 Tank	Temperature
	Growth Chamber	Temperature, Humidity

How Do I Monitor These Critical Environments?

There are two leading technologies used to electronically monitor your critical points, including stand-alone data loggers and networked central monitoring systems. There are several factors to consider when evaluating the right electronic monitoring solution for your organization.

You will want to take into account the number of points you need to monitor, the type of monitoring point(s) you want to monitor (i.e. temperature only or other parameters), your future needs to add additional monitoring points, the location of your monitoring points (on-site or at an auxiliary location), etc.

On the next page, **Table 1.3** will help you better determine which solution best fits your needs.

Perhaps not all questions in the table apply to your specific application, but use the questions as a guide and reference point to help you determine which solution best fits your needs.

Determine your monitoring solution (Table 1.3)

Ask yourself…	Stand-Alone Data Logger	Networked Solution
How many points / pieces of equipment do you need to monitor?	Few	Few to many
Does your site have multiple labs, nursing stations, storage rooms and / or facilities located across the world?	No	Yes
Do you need to be notified by phone or e-mail in case of an alarm?	No or Phone call only	Yes – Phone, E-mail & Text
Equipment or storage space at an auxiliary location or managed by a third-party?	Yes	No
FDA 21 CFR Part 11 Compliant?	Yes	Yes
Want real-time access to trends, alarms?	No	Yes
Future lab / facility expansion?	No	Yes

Stand-Alone Data Loggers – Few Pieces of Equipment and Auxiliary Locations

Ideal for: doctor's offices, off-site clinical trials, small laboratories, pharmacies

Stand-alone data loggers are small, highly accurate solid-state devices that are very simple to implement into regular processes. Data loggers have been around for several years, but newer models implement USB technology for fast and efficient data download, report sending and report archiving purposes.

Implementation depends on the data logger and your application. Some data loggers can be placed on a shelf or mounted to the side of a piece of equipment. Most data loggers have a display that will provide the operating conditions and alarm status. Some data loggers can connect to a telephone dialer.

Stand-alone data loggers are low maintenance and easy to use, making them ideal for doctor's offices, off-site clinical trials and other locations where your application may include auxiliary facilities and / or third-party testing sites.

Table 1.4 provides an overview of how simple it is to implement a stand-alone data logger into your daily and weekly routines.

Stand-alone data logger implementation (Table 1.4)

Daily
☑ Check data logger screen for alarm status
☑ If in alarm, plug data logger into USB and view report details immediately
☑ If screen reads OK, do nothing
Advantages: *When needed, e-mail report to quality manager for fast and easy analysis, without wasting time on handwritten reports!*
Weekly
☑ Plug data logger into computer USB
☑ Check PDF report
☑ Archive report
Advantages: *No chart replacements, no pen replacements, no chart storage, no special handling needed!* *Never stock chart paper and pens again!* *No more costly repairs!*

Networked Systems for Many Critical Points

Ideal for: pharmaceutical companies, hospitals, GxP facilities, universities

A networked system is fully automated and includes data loggers, sensors and software. This type of setup is often referred to as a Central Monitoring System (CMS). Sensors are strategically placed to monitor critical points, monitoring data automatically downloads to your system and alarm notifications are customizable.

Some systems offer multiple alarm delivery options such as e-mail, phone and SMS messaging. Software platforms vary, and can include options to accommodate audit trail requirements per GxP with 24/7 real-time access to the status of all critical points remotely. **Table 1.5** is an overview of advantages that a CMS solution offers.

CMS features & benefits (Table 1.5)

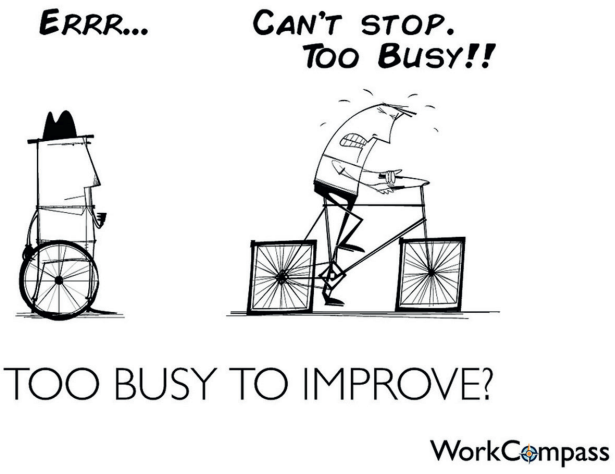
Feature	Benefit
Low risk to human error	Data automatically downloads
Scalable	Easy to add new equipment and points to monitor
Redundant	Data is stored in data logger and archived to server
Time savings	Automatic data downloads, analyze data fast and easy
Circumvent product loss	View trend data to determine when there are possible problems and take action

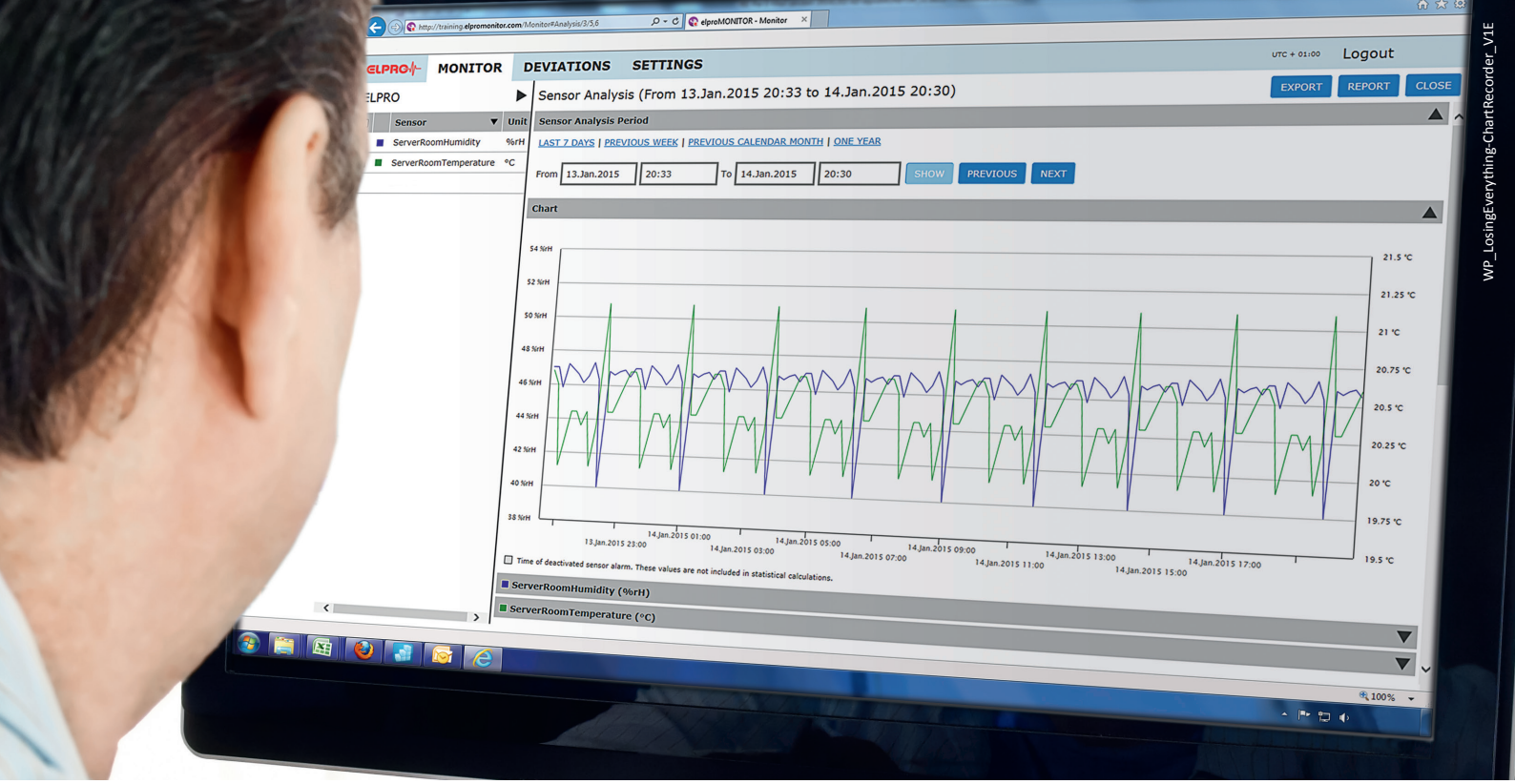
Perhaps the most significant advantage of a CMS system is that it provides the ability to circumvent product loss with real-time access to trend data. There is no other solution that will allow you to monitor the environmental trends like a CMS system. With programmable alarm notifications, you will receive text messages or can even view the status of your equipment from the comfort of your home on nights and weekends.

Conclusion

Implementing the right electronic monitoring solution provides your organization with traceable data, saves your operation time and ultimately protects your valuable products. Ask yourself how much the contents you are storing or testing are worth and choose the right solution based on what you have to lose. Time? Money? What is the impact of losing everything? The reality is that there is a lot to lose, so don't let your products or samples be at risk by relying on an archaic environmental monitoring technology.

We hope this presented an educational and applicable overview of environmental monitoring. Please contact ELPRO so we can help you implement a modern approach to environmental monitoring.





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