The background features a stylized circuit board pattern in blue and white. The board has several horizontal tracks and various vertical connections represented by small circles. Some of these connection points are highlighted with a bright white glow, suggesting active data points or nodes. A thick black diagonal band runs from the bottom left towards the top right, partially obscuring the circuit board pattern.

# Cryopak<sup>°</sup>

## REAL-TIME MONITORING SYSTEMS

6 Points to Consider to Choose the Best Option for You

# AUTHORS

## ***Denis Delia – Co-Author***

Denis Delia, Instrumentation Coordinator at Cryopak, has 10 years of experience in the pharmaceutical, biotechnology, and life science industries. He is specialized in instrumentation, calibration, installation of real-time monitoring systems, customer service and support.

Denis earned a certificate in Telecommunications and a certificate in Instrumentation from École Polytechnique, Quebec.

## ***Jalal Belbal, B.Sc. Eng. – Co-Author***

Jalal Belbal, Validation & Regulatory Compliance Manager at Cryopak, has over 10 years of experience in the pharmaceutical, biotechnology, and life science industries. He has worked on a wide range of qualification projects including mapping process, laboratory equipment, packaging and software validation to help the Life Science industry fulfill US and Canadian regulatory requirements and best practices.

Jalal earned a bachelor's degree in Biochemistry & Environmental Engineering from University Laval, Quebec.

## ***Geneviève Joseph – Co-Author***

Geneviève Joseph, Marketing Coordinator at Cryopak, has over 10 years of experience in retail sales & customer service. She joined Cryopak in 2012 as a documentation specialist, where she gained experience in mapping process and thermal equipment qualification. She joined the Sales & marketing team a year later.

Geneviève earned a certificate in Political Science and a certificate in Professional Writing from University of Montreal, Quebec. She is currently a McGill University student in Marketing.

*This material is subject to copyright protection, with all copyrights retained by Cryopak and its individual partners. The reproduction, transfer, distribution or storage of information contained in this document in any form without the prior written consent of Cryopak is strictly prohibited. All specifications — technical included — are subject to change without notice. This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only. All rights reserved.*



# TERMINOLOGY

## CALIBRATION

In metrology, calibration is the comparison of measurement values delivered by a sensor to those of a standard. Many companies use NIST standards. Every step of this process is clearly documented.

## POST-CALIBRATION

Documents the quality of the product throughout its life span from the moment it leaves our warehouse to the end of its yearly cycle. This process proves to regulatory agencies that the temperatures recorded throughout the recording period were accurate.

## NIST TRACEABLE

This means that a standard from the National Institute of Standards and Technology (NIST) was used to determine the sensor's bias, precision, and accuracy.

## ADJUSTMENT

Once the sensor's bias has been determined, its curve is adjusted in the system through extended calculation. This step ensures the data recorded and displayed by the system are reliable.

## ACCURACY

Accuracy refers to the level of proximity to the true value. For example, the temperature recorded by a sensor with an accuracy of 0.5°C and displaying 5°C could in reality be 4.5°C or 5.5°C.

## RESOLUTION

Resolution refers to the data point increments of the sensor. For example, if the temperature recorded by a sensor with a resolution of 0.0625°C is 1°C, the next data point recorded when temperature rises will be 1.0625°C .

## REDUNDANCY

RF redundancy refers to radio coverage of your environment. Redundancy is essential to ensure uninterrupted communication between the sensors and the system in case of equipment failure.

## STRESS TEST

Stress testing refers to a series of tests performed on the physical equipment to ensure it can stand up to any environmental conditions it might be exposed to. It often means exposing the unit to extreme temperatures for a specific period of time.

## REAL-TIME MONITORING: WHY?

Regulatory requirements have evolved quickly in recent years. The rules are more restrictive than ever, thus increasing the number of steps required.

### REGULATORY REQUIREMENTS

Most industries are now required by regulatory agencies to comply with strict quality standards. One of them is to monitor temperature and other environmental conditions at all times. While the regulation doesn't require real-time monitoring, the advantages can't be ignored.

---

### PROTECT YOUR PRODUCTS

Time is the essence when it comes to protecting your products from temperature variations. Real-time monitoring systems lets you know immediately if there's a problem with your products.

---

### REDUCE MANUAL LABOR

While real-time isn't a regulatory requirement, it can save your company valuable time by reducing manual labor to a minimum. The time when an employee had to manually record temperatures multiple times a day is now over. The system also keeps your valuable data safe since no documentation has to be kept physically.



# 1. TYPE OF ENVIRONMENT

*The first element to consider when choosing a real-time monitoring system is the type of environment to be monitored. The size and type of environment will greatly influence the solution that is the best suited to your needs.*

## TYPE OF ENVIRONMENT

Warehouse, cryogenic freezer, cold room: there are many types of environment, each with their specific challenges. The type of environment monitored will determine the type of sensor needed. Sensors can be external or internal, measure temperature or other environmental conditions, and be designed for a particular temperature range.

Your supplier will need to know any special requirements related to the environment to be monitored to specify the best solution for you.

## SIZE & LAYOUT

The size of the environment to be monitored will dictate the number of sensors required to provide the best coverage. However, the size isn't the only factor affecting the number of sensors required. It's also essential to take into consideration the layout of your environment. Walls could affect data transmission, thus requiring a larger number of sensors. Again, your supplier is the best person to define the number of sensors to use and where to place them.



## 2. CALIBRATION

*The calibration process is one of the most important elements to consider when choosing a real-time monitoring system. Over time, even the best measurement instruments will start to drift. Regular calibration and equipment maintenance is the only way to ensure your system continues operating within the original specifications throughout the years.*

### ON-SITE VS EXCHANGE PROGRAM

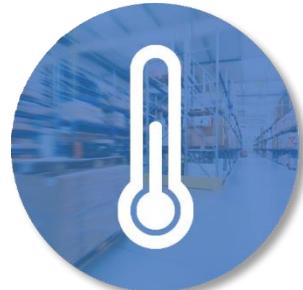
An on-site calibration program requires a technician to come to your facility. This saves you time since no labor is required from your own employees. However, this can interrupt your regular activities, and be more expensive if your supplier doesn't have an office in your area. It also involves some downtime to perform the calibration.

An exchange calibration program means that your supplier sends you newly calibrated sensors a few days before the old ones expire. This avoids any downtime and is less disruptive. However, it requires more labor on your part.

### CALIBRATION POINTS

Another essential aspect of a calibration service is the number of calibration points verified, and the calibration points used. The minimum number of points is two (2). There isn't any maximum, but we see rarely see more than 9 points in the industry. Just keep in mind that the higher the number of points, the more precise your calibration will be.

Calibration points are usually selected by your supplier to cover the measuring range of the unit. You can always request your own calibration points; however, be aware that requesting specific calibration points will increase the calibration price.



# 3. NETWORK

*Now that you've evaluated the number and type of components you need, and made sure the calibration process is right for you, it's time to choose a communication network. The industry uses two types of network: Wireless and wired connections.*

## WIRELESS

Wireless connections are the most popular option in the industry. Their popularity is due to the fact that they are easy to install and set-up, and are accessible almost everywhere. However, radio waves can be blocked by walls, requiring multiple overlapping access points. Wireless connections can also sometimes interfere with other devices in the area. This is why you need to take a close look at your environment to define the best option.

## WIRED CONNECTIONS

The most common form of wired connection is the Ethernet cable. It's part of a family of computer networking technologies commonly used since 1983. One of its biggest advantages is the absence of interference with any other devices in the area. The recording units can also be powered through the Ethernet cable, thus reducing manual labor. However, it's biggest disadvantage is the cabling required.



# 4. SYSTEM VALIDATION

*Make sure the supplier performs proper testing on both the hardware and the software to ensure compliance with regulations in force.*

## FACTORY ACCEPTANCE TEST (FAT)

The FAT is performed at the factory, before any piece of equipment is shipped. Its main purpose is to test the components' overall behaviour and ensure it meets a series of criteria in order to be approved for installation. It usually includes the following tests:

- Physical functionalities of the equipment (buttons, screen, etc.)
- Signal strength
- Stress test

## SITE ACCEPTANCE TEST (SAT)

The SAT is performed on-site, once the installation is completed. The components provided by your supplier undergo a series of tests defined in a protocol to ensure shipping didn't affect the equipment. It usually includes the following tests:

- Physical functionalities of the equipment (buttons, screen, etc.)
- Communication between the equipment and the server
- Radio coverage
- Redundancy
- Memory capacity

This can either be performed by the installer or yourself.

## SYSTEM VALIDATION

The final step is to perform the system validation. While FAT and SAT test the components' functionalities, the system validation covers the software's overall operation. It also ensures the system's conformity with major regulations, such as CFR 21 Part 11. The system validation is performed only once; changes made to the system afterwards are covered by a change control.



## 5. TYPE OF ALARMS

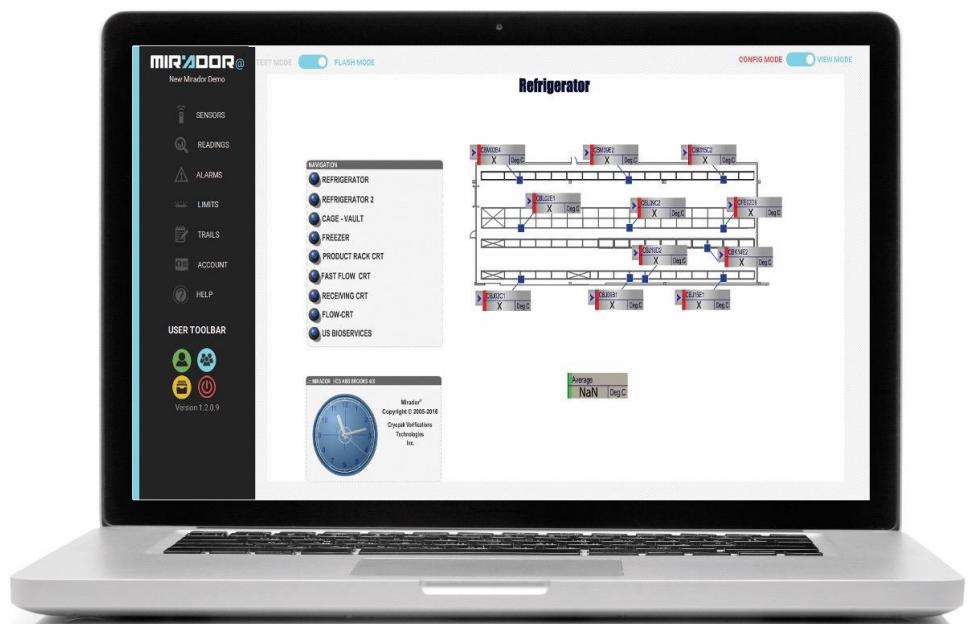
The main purpose of a real-time monitoring system isn't only to comply with regulations in force; it's to let you know a problem is happening before it affects your products. Therefore, the system's alarm capacity is a critical component.

### ALARMS

Most systems deliver alarms via email, text message, or pager. The message usually identifies where the alarm is located, and the type of alarm. To ensure appropriate actions are taken, most systems are capable of sending cascading alarms. If the first person doesn't react within a specific timeframe, the second is informed, and so forth. This ensures proper actions are taken before your products are affected.

### EXTERNAL ALARM COMPANY

To reduce the risk of product loss, most real-time monitoring systems can be linked to an external alarm company. Just like with regular alarm services, the external alarm company keeps a close eye on your installations.



# 6. MAINTENANCE & SUPPORT

*Once the real-time monitoring system is installed, you will still need to manage your database. You also need to define the level of support offered by your chosen supplier to avoid any surprises.*

## SYSTEM BACKUPS & LICENSES MANAGEMENT

To comply with most regulatory requirements, your data need to be accessible up to three years. Auditors can ask to pull up reports. However, your system can't keep all these data in its database because of the memory space it takes. This is why system backups are essential. Most systems are sold with a limited number of licenses. This limits the number of people that can be connected to the system at the same time. You will need to manage these licenses carefully to avoid any overlaps, especially when growing your team.

## SUPPORT

While every system is designed to work properly, no one is shielded from a system malfunction caused by a technical issue, or human error. This is when trust in your cold chain partner becomes crucial. Before making your decision, discuss worst case scenarios and procedures with your potential supplier to ensure the level of support they offer corresponds to your expectations.



## ABOUT CRYOPAK

Cryopak is a cold chain solutions provider for the pharmaceutical, life sciences, biotech and food industries. The company manufactures items for temperature-sensitive shipping needs, including insulated shipping containers, gel packs, phase change materials and temperature monitoring devices, and also offers package design and testing services in its ISTA certified labs. Cryopak delivers superior products and service from an industry-leading team of experts whose primary goal is to ensure and protect product integrity.

Cryopak is headquartered in Edison, New Jersey, with locations across the United States, Canada, and France.



### To Request a Quote

Quebec / Maritimes / Ontario  
1.888.423.7251  
[sales@cryopak.com](mailto:sales@cryopak.com)  
[www.cryopak.ca](http://www.cryopak.ca)

Western Canada  
1.800.667.2532  
[sales@cryopak.com](mailto:sales@cryopak.com)  
[www.cryopak.ca](http://www.cryopak.ca)