When looking to implement a Continuous Monitoring System, one of the many factors to consider is how well will the system meet your specific needs and the needs of your facility. The greater the customization of the system, the easier it is going to be to implement into your facilities’ SOPs and the more effective the system’s alarming capabilities will be when introduced to staff members and department heads. Rarely will one approach work for several areas so customization and flexibility of the system, its equipment and software can dramatically impact the usefulness and adoption of the system, especially for multidepartmental applications.

Not only must the system be able to monitor temperature, humidity and other critical parameters accurately and reliably, automatic and on-demand reporting must be readily available in order to meet accreditation guidance, client requirements and/or industry standards. After all, what good is all that data if you can't provide meaningful reporting and timely responses to inquiries?

Paramount to any Continuous Monitoring System are its capabilities when an alarm situation occurs. Varying the alerting by department, piece of equipment, time of day, day of the week, condition parameters, delivery method and escalation protocols can mean the difference between immediate/appropriate action and interaction, and coworker frustration and product loss.

In order to offer some guidance for those researching continuous monitoring systems, we have complied a listing of relevant questions to aid in the decision making process. The goal is to make sure that the system you are looking at will indeed meet your current needs and the expanding needs of the organization moving forward.

**Sensor Battery Life**

The typical duration of life for batteries used within a Continuous Monitoring System (CMS) may seem like minor detail, but the way that the system utilizes batteries and how they are maintained and replaced can dramatically impact cost of ownership, especially if a service call is required for replacement.

**Things to consider:**
- What type of batteries are required?
- Are the sensor batteries user replaceable?
- What is the life of the sensor batteries?
Calibration

Most governing bodies are increasing their requirements when it comes to traceable calibration of sensors used within a CMS. Suppliers vary greatly in that some do not offer a NIST-traceable certificate with new sensors and some also require on-site calibration as a yearly “add on” service.

Things to consider:
- What is the annual calibration process and cost?
- Can calibration be accomplished by the user?
- Is a certification of sensor calibration provided with the initial installation?
- Is a NIST-traceable certificate of calibration provided?

Network and Server Requirements

Depending on the architecture of the facility/department, organization-wide Wi-Fi strength and specific IT requirements, there are a number of different ways in which a CMS can be configured and installed. Often times, a system should be customized to reflect the specific attributes of your application in order to achieve the most usefulness and reliability from your monitoring system.

Things to consider:
- Does the system have both a 900MHz and Wi-Fi option for system communications?
- If 900MHz, does the system provide both Repeaters and Ethernet based Access Points?
- Can the system be installed on a local server or can it be hosted in the cloud to reduce cost of ownership?
- If local, is a dedicated server required? Can it be installed ‘virtually’ on an existing Hospital server?
- How does the system accommodate remote site installations?
- How does the system protect against interference with medical equipment and other devices?
- Is the system Web-based, providing remote access over the internet?
- If the network experiences an outage, how does the system compensate?
- Does the system hardware have integrated system back-up/buffering capabilities of the hardware components?
- Are network status reports and/or diagnostic tools available with the system?
- Will the system allow for multiple time zones or multiple languages?
The eyes and ears of any monitoring system, the sensors themselves are vital to any critical parameter being monitored. As the last line of defense, the accuracy and reliability of the sensors is vital to the effectiveness of any monitoring program.

As most systems are priced ‘per point’, it is important to understand the situations where an individual sensor can monitor multiple parameters. Because of the multitude of situations that you may want to monitor, it is also very important that the system’s sensors can accommodate a variety of parameters, locations and equipment. This planning will not only ensure that your current needs are met, but it will also prepare for system expansion should this be necessary in the future.

**Things to consider:**

- What is the maximum number of sensors accommodated by the system?
- Do the sensors have two-way communication with the server?
- Do the sensors come with the ability to also monitor Door Open/Closed?
- Do the sensors have internal memory? How much/how long?
- What other types of sensors are available?
  - a. Temperature and Humidity
  - b. Ultra Low Temperature (-80°C)
  - c. CO₂
  - d. Differential Pressure
  - e. Dual Temperature (top and bottom of combination units)
  - f. Liquid Nitrogen with Dry contact alarm status
  - g. Motion for Platelet Rotators
  - h. Temperature and Door Open/Closed Status
  - i. Dishwasher (hot water line)
  - j. Power/network outage
- Can a single sensor monitor multiple values, such as Temp & Humidity; Temp & Motion; Temp & Door open/close?
- Does the system meet the Pharmacy’s USP 797 requirement for Differential Air Pressure Monitoring?
- Are the sensors water-resistant?
- How is the system performance impacted upon loss of connectivity or system failure?
- Is there a sensor ‘low battery’ alarm?
- How does the system provide notification during communication loss with a sensor?
- Can you place a sensor in a ‘repair’ status to prevent unnecessary alarms?
The way that a system can alert its users to conditions outside of desired parameters varies greatly from system to system. Often times, different departments are responsible for separate pieces of equipment located in the same area and will need completely different alerting and alert escalation. This functionality can be quite complicated and it is necessary to understand if the system will meet the needs of every department head and technician required to be in the loop on your equipment.

Things to consider:
- Does the system offer alert escalation?
- Can alert escalation be 'looped'?
- Can the system program a different alert escalation path for each sensor based on the time of day and day of the week for non 24/7 areas?
- How many levels of escalation can be programmed for each event?
- Is there a local visual and audible alarm available?
- How does the system document corrective action?
- Can alert notification be programmed to respond based on the temperature exceeding the temperature parameter and also a time parameter?
- Does the system have an ‘alert threshold’ which will give the unit a chance to recover in the event of an out-of-range situation (e.g. door opened)?
- Does the system offer an alarm suppression feature which will allow for the flexible scheduling of alert suppression based on customer requirements?
- Does the system provide for departmental control of alarm limits under their control?
- Does the system alert if a component should fail like a Sensor, Repeater or Access Point?
- Does the system provide continuous System Status of Health (SOH) monitoring with automated alerts?
- If a component of the system should fail, is there a feature to identify the exact point of failure?

There are great variances in what is covered from system to system. Make sure you are comparing apples to apples when reviewing the warranty for continuous monitoring systems as the terms of the warranty can have a major impact on cost of ownership over time.

Things to consider:
- How long is the product warranted after initial installation?
- Are there any additional fees related to work done under warranty?
7  Service/Support

In order to get the most out of any continuous monitoring system, training and ongoing support are of utmost importance. From professional installation and installers to responsive after-the-sale service and support, this is the true measure of a professional solution and partnership. You need to be confident that the system you choose will be fully supported for years to come and that the organization you work with is structured so as to be able to meet your needs in a timely fashion.

**Things to consider:**
- Is complete system installation and setup provided by the manufacturer?
- What are your Service and Extended Warranty options
- Are software upgrades provided as part of the service contract? How is the software upgraded?
- Is system training provided as part of the installation?

8  Reporting and Compliance

Preparing the data for various reports should not only be simple, it should be automatic! Many systems now offer the flexibility to automatically produce and print/save reports on a daily/weekly/monthly basis and are fully customizable based on your needs and preferences. You can also create very different reports based on departmental needs and any particular regulatory requirements. Systems can be configured to require input from those receiving the alarm so that it is documented that they acknowledged the event. Any action can be documented as well, keeping your facility in compliance and your documentation complete.

**Things to consider:**
- Does the system provide centralized administration (passwords, etc) and global administration of a single database?
- Does the system provide for departmental control of alarm limits under their control?
- How are users, equipment and alert notification grouped within the system?
- Does the system meet the stringent requirements of Blood Banks including:
  a. Calibration with NIST Traceability
  b. Alarm check
  c. Validation IQ/OQ
  d. Temperature monitoring of upper & lower sections of Blood Bank Devices
- Is the system FDA 21 CFR Part 11 compliant?
- For Blood Bank/Transfusion Medicine applications (e.g. frequency of temperature determinations, frequency of reporting to application software, if dual probes), is delta difference between the two customizable for alerts?

As part of any RFP/quote request, the hospital should provide as much information as possible to ensure an accurate price quote. This would include:
- A list of the devices to be monitored including the type of sensor required as described above. Please note any combination units for upper/lower temperature monitoring. A template for gathering this data can be provided upon request.
- Floor plans with the location of each device identified. This is especially important for a 900MHz System and will help us determine the appropriate infrastructure to install.