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Top considerations for choosing the correct monitoring system.

This guidance document provides information, recommendations, and resources to assist you in sourcing for a continuous monitoring system. These considerations were developed with Testo's 60+ years of life sciences temperature measuring manufacturing experience and regulatory guidance. When considering a continuous monitoring system, it's important to understand how the system works from sensor communication type, to data security, and alarming and escalation. Here are the top 6 considerations when looking for the continues monitoring system. For specific details on FDA regulatory info visit https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application or https://www.fda.gov/

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Functional Requirements

Consider and discuss internally your basic requirements that the monitoring system should have.
As a start you should be considering:

- For compliance purposes, what regulatory requirements must you adhere to?
  - FDA 21 CFR part 11
  - CDC's current storage and handling guidance toolkit
  - USP 1079, USP 797
  - WHO Annex 2
  - EU Annex 11
- What environmental quality parameters do I need to collect?
  (temperature, relative humidity, differential pressure, etc.)
- What type of chamber or room and measurement ranges need to be monitored?
  Refrigerators? Freezers? Incubators? Stability chambers? Etc.?
  - Recommended uncertainty of sensors example: +/-0 .5° C (+/-1° F).
  - How often do I need to record temperatures, and does the system allow for configurable data recording intervals?
  - How will the monitoring system communicate within the facility? WIFI, Radio Frequency, Ethernet sensors?

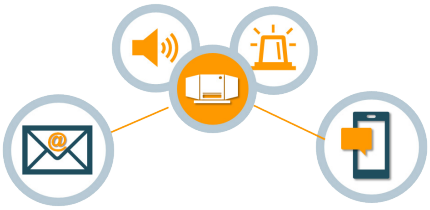
Data Integrity

Consider a system that offers the highest level of data integrity and security. When considering a system for your life sciences facility you should consider:

- 21 CFR Part 11 Compliance, which includes:
  - A detailed audit trail, detailing users' activity, and actions within the system
  - Electronic signatures on actions performed within the system
  - Controls for electronic records, ensuring data integrity
- Configurable user permissions, with individual rights based on level of clearance.
  Admin, Power User, or User
- Protection of records with the ability to retrieve records for entire systems
- Manual or automatic system backup

Alarm Functionality

One of the many advantages of an automated continuous monitoring system is the custom configurable alarming functionality. Customers should consider a system that offers the following alarming functions:

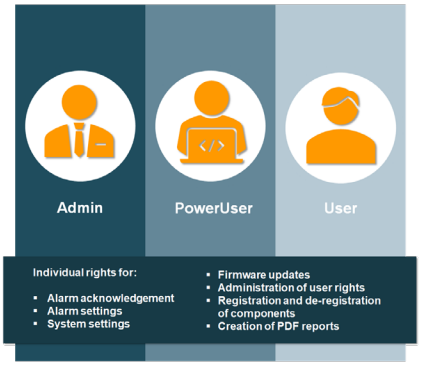


- Alarming at low and high temperature set points, lost connection, and low battery or power loss
- Configurable user permissions, with individual rights based on level of clearance.
  Admin, Power User, or User
- Protection of records with the ability to retrieve records for entire systems
- Manual or automatic system backup

Security and Redundancy

Consider a system that offers multiple layers of security and data redundancy of your electronic data collection. Considerations of security and redundancy are:

- Multi-levels of security for administrative, operational and view only functionality
- Archived data securely protected and always accessible
- Individual pieces of equipment must have internal memory and intelligent interconnection acknowledging data transfer before data is overwritten
- Data recovery and continuous recording even in the event of power outage or loss of communication



Reporting and Interface

Another major advantage of an automated continuous monitoring system is the organizational interface and reporting functionality. Consider the following functions when choosing a monitoring system:

- System capability of producing reports and scheduling automatic reports to be sent via email on a daily, weekly, monthly, quarterly, and/or annual basis.
- Generate reports as it relates to audit trails, alerts, alarms, and trending data
- User interface should include optional remote access of data on personal computers, tablets, and smart phones
- Interface should include an option for a custom layout of the facility with sensor placements and the ability to drill down and view data, environmental trends, and alarms

Professional Services

When considering a potential system, be aware of the vendors ability to perform professional services to ensure the highest level of quality and assurance. Consider these professional services to go with your system of choice:

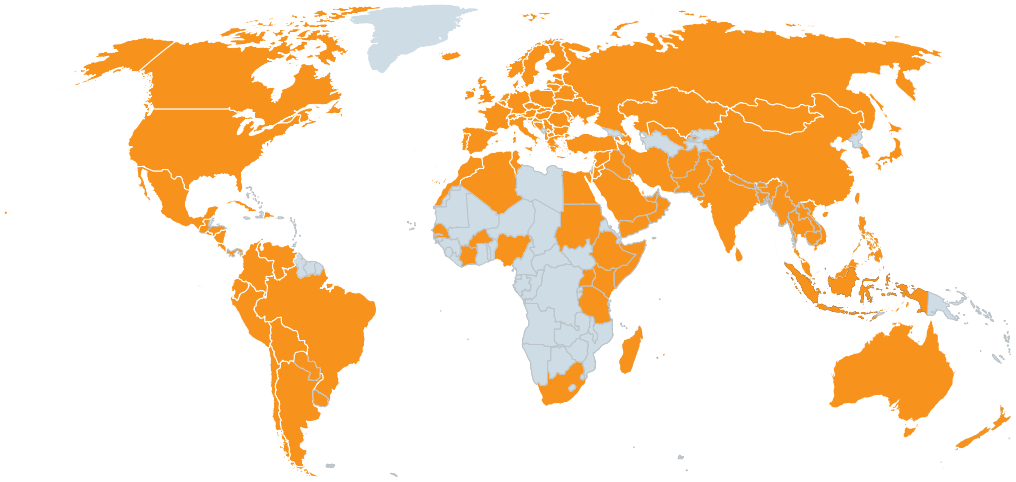
- Installation Qualification, Operational Qualification, Performance Qualification Packages
- Calibration Services performed by an accredited ISO: 17025 laboratory
    - o A plan for ongoing recalibration of sensors
- Thermal mapping services to identify worst case scenarios in your facility
- A reputable vendor with a quality management program in place such as ISO:9001 2015

Testo:
High-tech from the Black Forest.

Testo is a world leader in the design, development, and manufacture of innovative products and services for environmental and industrial measurement. For more than 60 years, leading companies in the life sciences industries have relied on Testo to help protect their products.

Testo's first product was a simple electronic thermometer. Today, the product line has expanded to include a large variety of critical measuring instruments, such as data loggers, air velocity meters, humidity and dew point meters, sound, pressure, and light meters.

With over 2,700 employees in 33 offices worldwide, Testo understands local requirements and culture. Testo currently has hundreds of thousands of data loggers in the market, storing over 17 billion data sets.



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