ColdStream®Site

Facility and Equipment Monitoring Service for Visibility and Compliance

Global regulatory and standards-based guidance documentation highlights the need for temperature, humidity and condition monitoring in controlled environments such as manufacturing, packaging/repackaging, laboratory, clinical, wholesale, distribution, pharmacy and logistics service provider operations. Increased regulatory scrutiny of drug-holding operations and the regulatory position that current Good Manufacturing Practices (cGMPs) apply across the entire supply chain necessitate the requirements for appropriate maintenance and documentation of storage conditions.

The ColdStream® Site Facility Monitoring Service is a wireless offering that automates the process of temperature, humidity, and condition monitoring in controlled environments. In a time of increased scrutiny, the ColdStream Site service helps companies comply with regulations and current Good Manufacturing Practices (cGMP) for the safe storage of pharmaceuticals. Areas monitored may include refrigerators, freezers, cold rooms and freezer rooms—anywhere temperature-sensitive materials and products are held. In addition to electronic record keeping and reporting, the ColdStream Site service automatically alerts designated staff when an excursion occurs, informing them when conditions have deviated from set parameters.

Features and Benefits

- Flexible, wireless sensor network that supports both large and small environments
- Easy-to-use, non-disruptive deployment—no need for expensive hard-wired infrastructure
- Cost-effective, automated record keeping eliminates manual clipboard checks
- Secure, encrypted data management keeps your records safe through centralized data administration
- Global access to information when and where you need it— by sensor, by room, by facility
- Real-time alarming and alerting for temperature compliance and product quality assurance
- Improved visibility and compliance through online data history and audit trail—designed to comply with 21 CFR Part 11

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The ColdStream® Site Service Overview

The ColdStream® Site service is a fully integrated solution for facility temperature, humidity and condition monitoring which combines wireless sensors with a dedicated wireless reader network and a Software-as-a-Service (SaaS) web portal.

- TempTale® Site wireless sensors are configured with user-defined alarm thresholds and measurement intervals. They are strategically placed inside any number of storage areas to record environmental conditions.

- TempTale Site wireless sensors record data and transmit the encrypted information wirelessly to a local ColdStream Site Network Controller.

- The ColdStream Site Network Controller relays the information to the ColdStream Site Web Portal. All data

is stored securely and is accessible to authorized users via a web browser; additional software is not required.

- The ColdStream Site Web Portal provides immediate access to real-time and historical sensor data for all monitoring locations—anytime, anywhere. Reports are available on demand or can be scheduled using a report wizard which will generate and distribute reports automatically via e-mail or fax.

- When an excursion occurs, designated personnel can be alerted through audible/visual alarms, as well as through e-mail, text or automated phone call. Once a problem has been identified and corrective action has taken place, the incident can be recorded in the system's historical audit log.

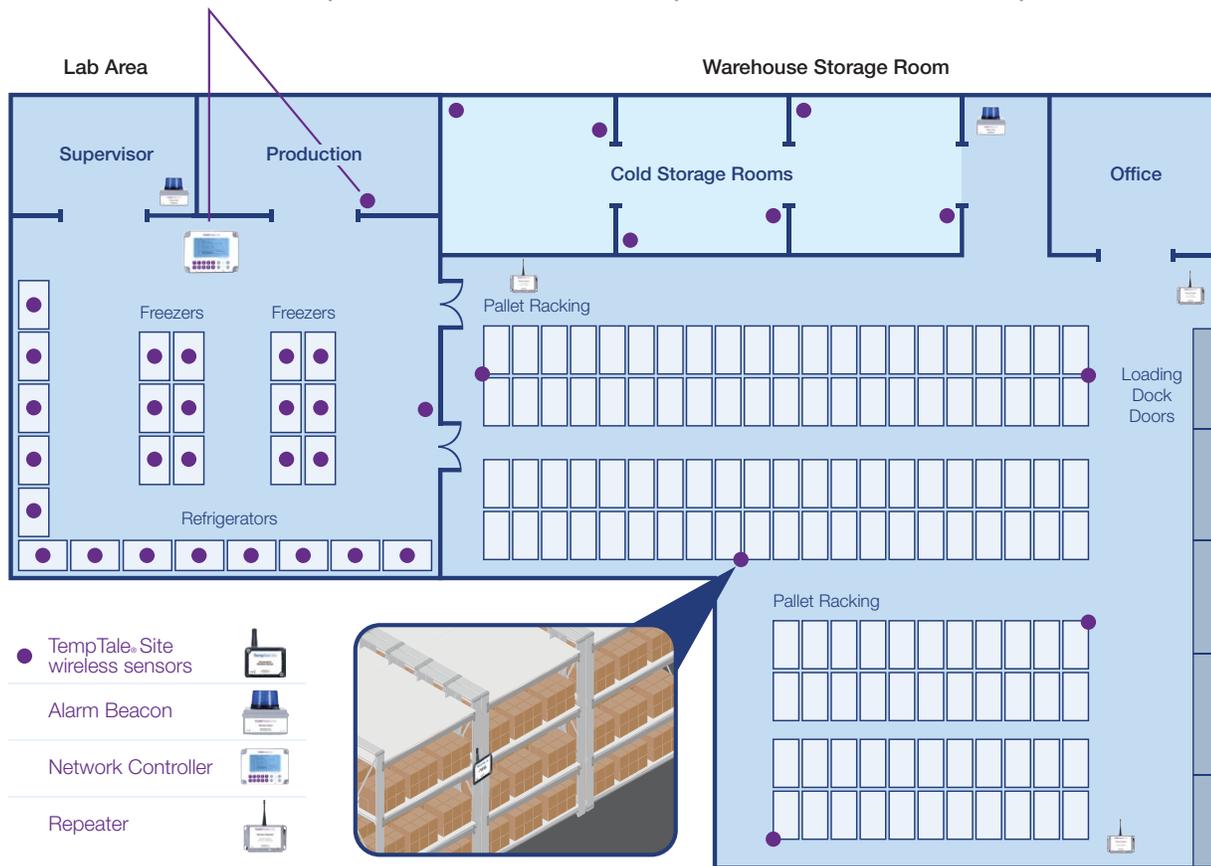The TempTale Site wireless sensors communicate with the ColdStream Site Network Controller.

Data transmits via Internet to the hosted, secure ColdStream Site Web Portal.

Alerts can be delivered by alarm beacon, email or text message.

The ColdStream Site Network monitors your facility for visibility and compliance.

Lab Area

Warehouse Storage Room

Supervisor

Production

Cold Storage Rooms

Office

Freezers   Freezers

Pallet Racking

Loading Dock Doors

Refrigerators

TempTale® Site wireless sensors

Alarm Beacon

Network Controller

Repeater

Pallet Racking

Information Where and When You Need It

The ColdStream® Site Web Portal makes data access and reporting easy. The portal's dashboard and site map provide immediate access to key information regarding the current state of all monitored locations. The dashboard highlights current sensor alerts, while the site map provides a quick overview of all sensors, their current readings, and their current status (e.g., normal, warning, or critical).

Information is delivered in the format your organization prefers; data can be viewed on demand or downloaded in multiple formats (e.g., .pdf, .xls, .csv formats) for a given day, week, or specific time period. Reports can also be scheduled for automated daily/weekly electronic delivery through the Report Wizard.
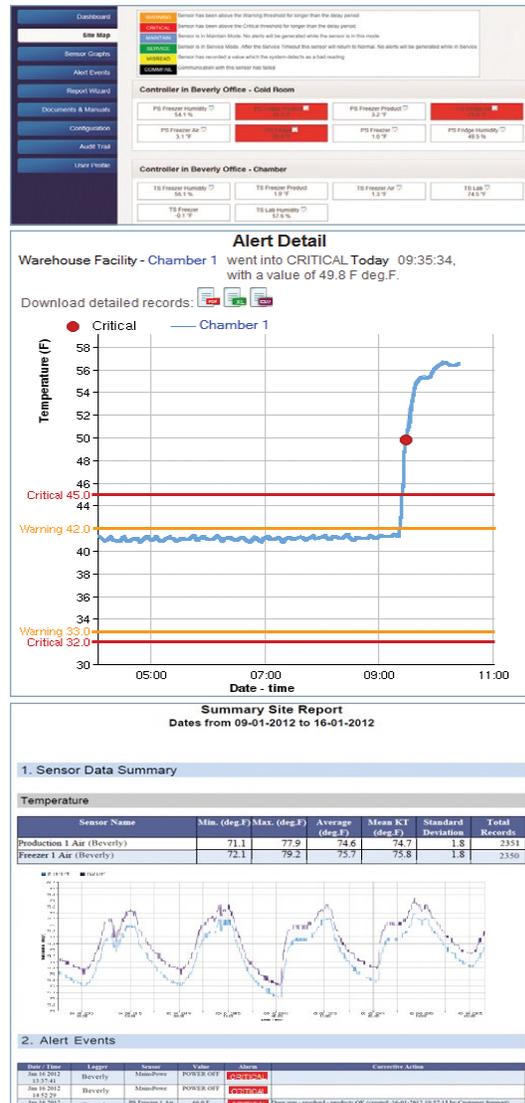
Alarming and alerting capabilities are key features of the ColdStream Site Facility Monitoring Service. The service can alarm on sensor-level readings (i.e., temperature excursions) or system-level issues such as damage to or removal of sensors, power failure, device malfunction, and network connectivity loss. Each alert can be configured to notify designated personnel through a variety of methods: local audible/visual alarm beacons, email message, text message, or automated phone call.

- Audible/visual alarm beacons can be installed at various high-visibility points within the facility to alert on-site staff that an excursion or system-level issue needs attention. Beacons can be configured to alarm for an individual sensor or group of sensors.

- E-mails and text message alerts can be configured to reach designated personnel with information that includes the exact location and details of the alarm. Escalating, automated phone calls can also be made to designated personnel until someone logs in, investigates the alarm, and takes action.

Corrective actions can be used to document your process controls. Once an excursion has occurred, corrective actions can be entered by authorized users. A user can select from a pre-defined list or can manually enter a corrective action as needed. Every corrective action entered is date and time stamped and includes electronic signatures.

Electronic record keeping helps to assure that you have a robust audit trail when needed. The ColdStream Site service maintains a rigorous 21 CFR Part 11 compliant audit log, tracking user and system activities including configuration changes, user logins, alerts, and corrective actions.

Your data is secure using a variety of methods. Access is protected by username and password authentication. Depending on their responsibilities, personnel can be granted different levels of access including read-only, read/write or full access to add corrective actions and sign-off data. In addition, all data transmissions are encrypted for security assurance.

Thermal Mapping Guidance

Global regulatory and standards-based guidance for the storage, handling, and distribution of temperature sensitive medicinal products recommends that facilities and equipment used to hold medicinal products be thermally mapped. This recommendation is based on the expectation that a company's Quality Management System (QMS) will include documentation to support that a state of control be maintained in a storage location, and that the rationale behind the chosen location for each sensor in a facility or equipment is sound. Since a thermal mapping will serve to document the science behind the monitor placement protocol used in the on-going monitoring system and prevent a company from being exposed to unnecessary regulatory risk, it is highly recommended that a thermal mapping be completed prior to installation of a stationary monitoring system.

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ColdStream® Site Wireless Network Components

ColdStream Site Wireless Communication Network

ColdStream Site Network Controller is responsible for collecting information from the TempTale® Site wireless sensors and relaying it to the ColdStream Site web portal via SMTP. The unit is AC powered with battery backup and communicates to the network via an Ethernet connection. Other communication options are available upon request. Each network controller can support up to 250 sensor channels. Additional network controllers can be installed, allowing for an even greater number of sensors.

ColdStream Site Wireless Repeater is used to extend the read range of the wireless network and is AC powered with battery backup.

TempTale Site Wireless Sensors

TempTale Site Temperature Wireless Sensor monitors both air and product temperatures. Product temperatures are simulated via a second temperature sensor embedded in a silicone gel.

TempTale Site Temperature and Humidity Wireless Sensor monitors both air temperature and humidity.

TempTale Site Wireless Cryogenic Temperature Sensor is suitable for liquid nitrogen applications and other extremely low temperature conditions. The sensor comes with a seven-strand thermocouple cable insulated with overall clear Teflon to provide extra strength and protection against rough handling and extreme temperatures. The unit is AC powered with battery backup in the event of a power failure.

TempTale Site Temperature and Door Ajar Wireless Sensor tracks air temperature and door open/close events. The sensor can be configured to alarm when the door has been left open for longer than a user-defined time frame.

TempTale Site 4-20 mA Wireless Transceiver will enable you to attach up to two standard two-or three-wire 4-20 mA transmitters to monitor other facility conditions such as shock or vibration. Alarm event conditions are user defined and configured based on the interpreted value measured and the duration of the event. The unit is AC powered with battery backup in the event of a power failure.

TempTale Site Wireless Sensor Specifications (by logger type)

	Temperature	Temperature and Humidity	Cryogenic	Temperature and Door Ajar
Read Range (Line of Sight)	up to 100 m (328 ft)	up to 100 m (328 ft)	up to 100 m (328 ft)	up to 100 m (328 ft)
Frequency Bands	868 or 915 MHz	868 or 915 MHz	868 or 915 MHz	868 or 915 MHz
Temperature Range	-35°C to +40°C (-31°F to +104°F)	0°C to +50°C (+32°F to +122°F)	-200°C to 0°C (-328°F to +32°F)	-30°C to +40°C (-22°F to +104°F)
Temperature Accuracy	+ 0.5°C (+ 0.9°F)	±1.0°C (±1.8°F) [Range 0°C to +5°C (+32°F to +41°F)] ±0.5°C (±0.9°F) [Range +5°C to +45°C (+41°F to +113°F)] ±1.0°C (±1.8°F) [Range +45°C to +50°C (+113°F to +122°F)]	+ 2.0°C (+ 3.6°F) [Range 0°C to -100°C (+32°F to -148°F)] + 5.0°C (+ 9.0°F) [Range -100°C to -200°C (-148°F to -328°F)]	+ 0.5°C (+ 0.9°F)
Temperature Resolution	0.3°C	0.1°C	0.1°C	0.3°C
Humidity Range	—	10% to 90%, non-condensing	—	—
Humidity Accuracy	—	+5%	—	—
Humidity Resolution	—	0.1%RH	—	—
Data Storage	5,461 data points	5,461 data points	5,461 data points	5,461 data points
Battery Life	5 years	5 years	5 years	5 years
Battery Type	Lithium TiCl 3.6V 2Ahr	Lithium TiCl 3.6V 2Ahr	NiCd 1.2V 1Ahr	Lithium TiCl 3.6V 2Ahr
Configurable Measurement Interval	5 to 100 minutes	5 to 100 minutes	5 to 100 minutes	5 to 100 minutes
Alarm Function	High/Low warning High/Low critical	High/Low warning High/Low critical	High/Low warning High/Low critical	Door open alarm High/Low warning High/Low critical
Typical Dimensions	65 W x 50 H x 36 D (mm) (2.6 W x 2.0 H x 1.4 D (in))	65 W x 50 H x 36 D (mm) (2.6 W x 2.0 H x 1.4 D (in))	108 W x 108 H x 58 D (mm) (4.3 W x 4.3 H x 2.3 D (in))	65 W x 50 H x 36 D (mm) (2.6 W x 2.0 H x 1.4 D (in))
Weight	108 g (3.8 oz)	113 g (4.0 oz)	181 g (6.4 oz)	108 g (3.8 oz)
Certifications & Industry Standards	NIST®/UKAS® traceable; Certificate of Validation	NIST/UKAS traceable; Certificate of Validation	NIST/UKAS traceable; Certificate of Validation	NIST/UKAS traceable; Certificate of Validation

Device Output Power

	Network Controller	Network Repeater	Standard Wireless Sensor
Output Power	200mW	1000mW	10mW

Sensitech Inc. is focused on delivering supply chain visibility solutions that track, monitor and protect products for global leaders in the food, life sciences, consumer goods, and industrial markets. Our solutions are focused in three key areas: quality and compliance, supply chain security, and logistics performance management. Quality and compliance solutions address temperature-sensitive, complex supply chains focused on delivering the highest quality possible, while our supply chain security solutions help to mitigate risks associated with theft, diversion and chain of custody. Sensitech's logistics performance solutions deliver origin-to-destination, real-time transparency to any in-transit journey. Sensitech Inc. is an ISO 9001:2008 company, headquartered in Beverly, Mass., with more than 35 sales, service and distribution locations around the world. Sensitech is a part of UTC Climate, Controls & Security, a unit of United Technologies Corp., a leading provider to the aerospace and building systems industries worldwide. Visit www.sensitech.com for additional information. © 2017 Sensitech Inc. All Rights Reserved. Unless otherwise indicated, all trademarks and service marks are the property of Sensitech Inc. NIST is a registered trademark of The National Institute of Standards and Technology Agency of the United States Government. UKAS is a registered trademark of the United Kingdom Accreditation Service.

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