



ColdStream® Site

Drive Visibility, Compliance and Reduce Waste

Stationary Monitoring Solution (-200°C to +50°C)

ColdStream® Site Stationary Monitoring is a wireless solution that automates monitoring of temperature, humidity and condition of controlled environments for life sciences manufacturing, packaging/repackaging, laboratories, clinical pharmacies, retail pharmacies, incubators, wholesalers, distributors, and logistics service provider operations. This solution was developed for pharmaceutical products monitored in refrigerators, freezers, cold rooms and freezer rooms. This stationary monitoring service is designed to meet global regulatory and Good Distribution Practices (cGDP), driving the need for automatic visibility alerting and 21 CFR electronic records documentation of storage conditions. Extremely flexible, this solution is able to adapt based on your changing and growing needs, providing consistent reporting of stationary monitoring for your operation around the world. Sensitech, additionally helps companies with thermal mapping projects, creating temperature profiles and determining improper variability within any stationary location or trailer, including warehouses, trailers, intermodal containers, and air cargo holds.

Features and Benefits

- Stationary wireless sensor network supports monitoring of large and small controlled environments
- Service model provides ease of set-up, use and maintenance
- Automated, validated, encrypted data management and record keeping
- Real-time alarms and alerts with global access and availability to data
- Global accessible Web Portal for all stationary cGDP operations
- Reduce risk of data loss with redundant storage back-up and on-board data storage within sensors and network controller
- 3-Point NIST traceable calibration with certificates of calibration
- Global technical support 24 X 7 X 365



ColdStream[®]Site

ColdStream Site Solution Overview

ColdStream Site is a fully integrated stationary monitoring solution which combines wireless sensors with a dedicated wireless reader network and hosted Web Portal.

- TempTale Site wireless sensors are factory configured to customer defined alarm limits and measurement intervals. The sensors are strategically placed to record environmental conditions.
- The sensors record data and transmit wirelessly to a local Network Controller (extremely scalable).
- The Network Controller relays information to the Web Portal. All data is stored securely and is accessible only by authorized users via the Web Portal; no additional software is required.

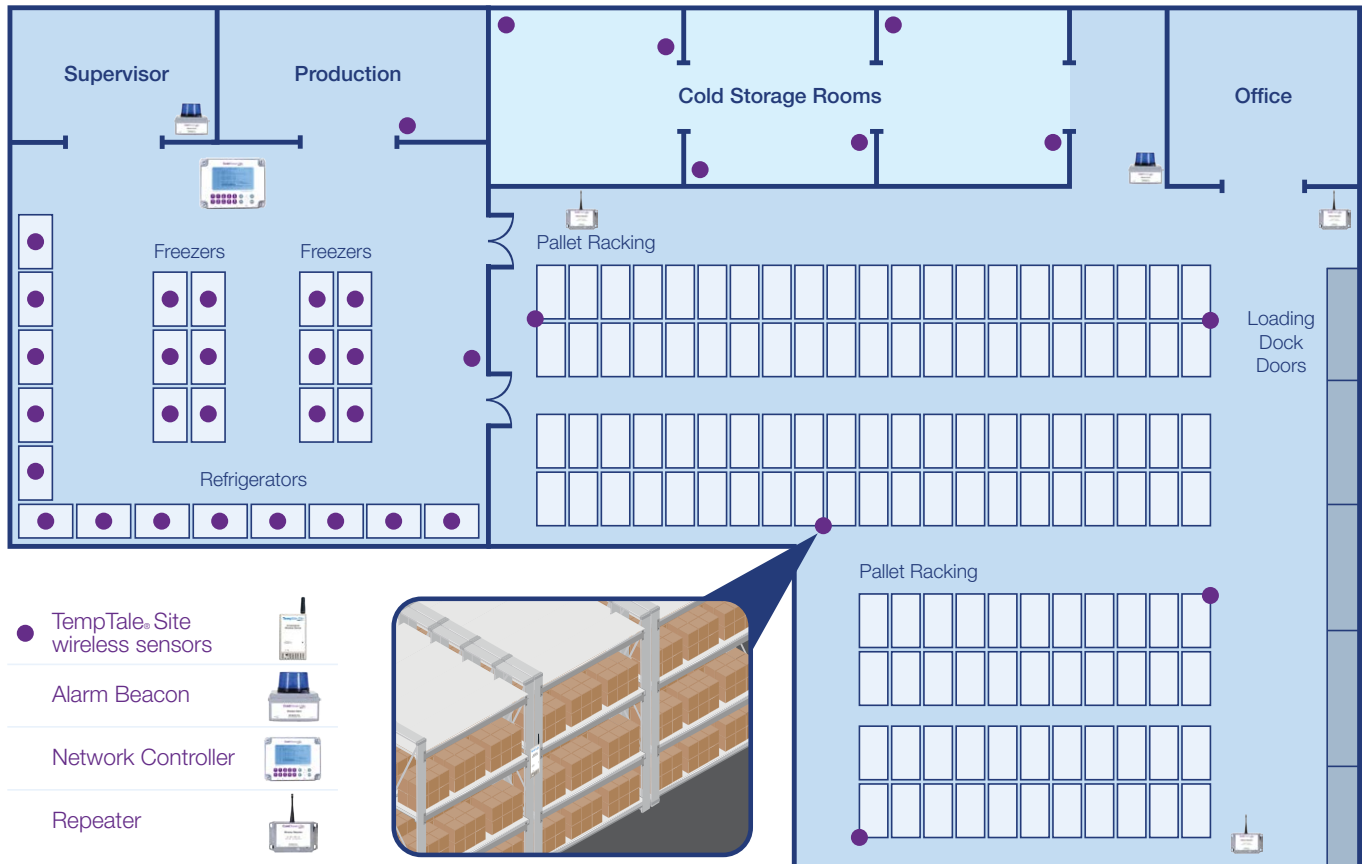
- Global access to the Web Portal provides real-time and historical condition data for all monitored locations. Reports available on-demand or can be scheduled for distribution automatically.
- Alerts communicating temperature excursions can be provided via email, text, phone call, audible or visible alarms. The system will record an event and can record corrective actions once they have been registered, also recorded in the audit log (21 CFR Part 11 ready).



Lab Area



Warehouse Storage Room



ColdStream Site Wireless Network Components

Network Controller: sensors wirelessly communicate data to the network controller which sends data up to the Web Portal via SMTP. AC powered with battery back-up and communicates via Ethernet connection (other options available upon request).

Wireless Repeaters: use to extend the read range of the network—AC powered with battery back-up.

Wireless Sensors: monitor both air and product temperatures designed to simulate probe in glycol/glass beads including, Temperature, Humidity, Cryogenic, and Door Ajar.

Alarm Beacons: visual and audio alerting available in both wireless and wired options.

4-20 mA Wireless Transceiver: add additional sensors to monitor other facility conditions such as O₂, CO₂, Pressure Differential, Light, Water, etc.

Thermal Mapping Consulting Service

A thermal mapping study is a critical step in understanding temperature risks in your storage environment. Use Sensitech's thermal mapping score methodology to determine worst-case positions to justify your permanent monitoring positions to reduce risk and be audit ready.

Dashboard

Site Map

Sensor Graphs

Alert Events

Report Wizard

Documents & Manuals

Configuration

Audit Trail

User Profile

WARNING Sensor has been above the Warning threshold for longer than the delay period

CRITICAL Sensor has been above the Critical threshold for longer than the delay period

MAINTAIN Sensor is in Maintain Mode. No alerts will be generated while the sensor is in this mode

SERVICE Sensor is in Service Mode. After the Service Timeout this sensor will return to Normal. No alerts will be generated while in Service

MISREAD Sensor has recorded a value which the system detects as a bad reading

COMMFAIL Communication with this sensor has failed

Controller in Beverly Office - Cold Room

PS Freezer Humidity 54.1%	PS Fridge Product 24.5°C	PS Freezer Product -15.9°C	PS Fridge Air 24.4°C
PS Freezer Air -16.0°C	PS Fridge -25.0°C	PS Freezer Air -17.2°C	PS Fridge Humidity 49.5%

Controller in Beverly Office - Chamber

TS Freezer Humidity 56.1%	TS Freezer Product -16.7°C	TS Freezer Air -17.0°C	TS Lab 23.6°C
TS Freezer -18.0°C	TS Lab Humidity 57.6%		

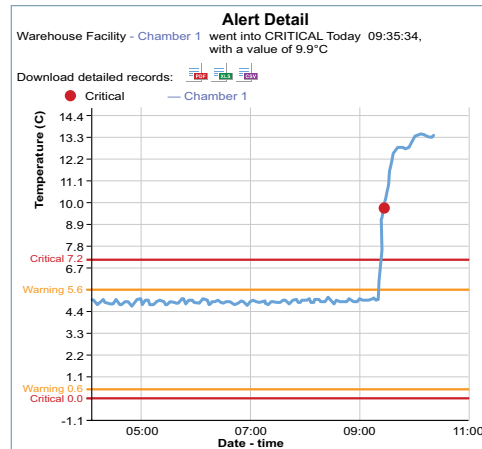
Summary Site Report
From 1 Feb to 2 Feb included

1. Sensor Data Summary

Sensor Name	Min. (°C)	Max. (°C)	Average (°C)	Mean KT (°C)	Standard Deviation	Total Records
Production 1 Air (Beverly)	-15.7	-11.7	-15.4	-15.3	0.6	568
Freezer 1 Air (Beverly)	-17.2	-12.8	-16.5	-16.4	0.7	567

2. Alert Events

Date/Time	Logger	Sensor	Value	Corrective Action
01 Feb 07:15:00	Beverly	MainPower	CRITICAL	
02 Feb 07:15:00	Beverly	PS Freezer 1 Air	CRITICAL	Door ajar + resolved + products OK (created by Cust Supt)



ColdStream Site Solution provides a variety of TempTale Site sensor options (additional sensors upon request).

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	0°C to +50°C	-200°C to 0°C	-35°C to +40°C
Temperature Accuracy	±0.5°C	±1.0°C (Range 0°C to +5°C) ±0.5°C (Range +5°C to +50°C)	±2.0°C (Range 0°C to -100°C) ±5.0°C (Range -100°C to -200°C)	±0.5°C
Temperature Resolution	0.1°C	0.1°C	0.1°C	0.3°C
Humidity Range / Accuracy* / Resolution	—	10% to 90%, non-condensing; ±5%; 0.1%RH <i>*RH Accuracy stated within Temperature Exposure Range of: 5°C to +50°C, Non-Condensing</i>	—	—
Probe Type	Probed (90 cm cord)/Probeless	Probeless	Probed (3 m cord)	Probeless
Data Storage	5,461 data points	5,461 data points	5,461 data points	5,461 data points
Battery Life/Type	5 year operating life— 3.6v lithium non-replaceable	5 year operating life— 3.6v lithium non-replaceable	5 years operating life— 12VDC 1A, 4 x 1.2V NiMH backup	5 year operating life— 3.6v lithium non-replaceable
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	80 W x 130 H x 30 D (mm) (3.1 W x 5.1 H x 1.2 D (in))	80 W x 130 H x 30 D (mm) (3.1 W x 5.1 H x 1.2 D (in))	148 W x 94 H x 35 D (mm) (5.8 W x 3.7 H x 1.3 D (in))	65 W x 50 H x 36 D (mm) (2.6 W x 2.0 H x 1.4 D (in))
Weight	140 g (4.9 oz)	140 g (4.9 oz)	380 g (13.4 oz)	120 g (4.2 oz)
Quality Assurance & Certifications	3-Point NIST®/UKAS® traceable Certificate of Calibration; FCC; CE	3-Point NIST®/UKAS® traceable Certificate of Calibration; FCC; CE	3-Point NIST®/UKAS® traceable Certificate of Calibration; FCC; CE	3-Point NIST®/UKAS® traceable Certificate of Calibration; FCC; CE

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