Environmental Monitoring Solutions

Be it operating rooms, clinical laboratories, pathology, nursing or administering temperature sensitive pharmaceutical drugs, manual environmental (e.g., temperature) logging is time consuming and prone to error. When hospitals, clinics and pharmacies have to prepare and submit compliance reports, manually recorded data logs require tedious compiling to governing agencies, such as the CDC, FDA, Joint Commission, HACCP and State Boards. The best practice in alleviating manual monitoring challenges is to install a real-time and continuous wireless environmental monitoring solution in critical areas where assets are stored such as blood banks, pharmaceutical and laboratory refrigerators.

Environmental monitoring requirements established by governing agencies all have unique conditions. Real-time and continuous data collection enables expedited reporting through electronic and digital logs, rather than manually compiled information. Using CenTrak's environmental monitoring solution, historical logs are maintained in a central database for healthcare organizations to reference in the event of an audit or legal inquiry.

Avoiding spoilage of high-value pharmaceuticals, samples, blood and more is critical as losses are often extremely costly and potentially dangerous to patients. When conditions are out of normal range, assets can be compromised creating concern and placing patients at risk. Even with a state-of-the-art facility and the best-trained staff, acts of nature and human error can occur. Without a real-time solution in place, staff cannot be proactively notified of any environmental change and sometimes temporary power supplies cannot maintain conditions without proper notification to key personnel.

To ensure patient safety and regulatory compliance, CenTrak's environmental monitoring solution can help to ensure sensitive items are maintained within predetermined environmental ranges. CenTrak's solution can help to ensure these requirements are met and proactively notify healthcare personnel via email, SMS, phone call, and/or pager when any item registers outside the acceptable parameters.

Missed logging times is a typical issue that occurs due to the tedious and repetitive nature of the task; this is exacerbated by frequent shift changes, vacation time, or changes in personnel. By having a continuous logging process, productivity is increased and risks are averted.

Measurement Capabilities

The measurement capabilities of CenTrak's environmental monitoring solution is listed below.

Description	Display	Accuracy	Measurement Range		Sensor Data Storage	Probe Type		NIST Type	
			Port 1	Port 2		Digital	RTD-Analog	Swap	Eng. Tool
Standard Temp	✓	+/- 0.5 °C	-40 °C to +100 °C	-40 °C to +100 °C	30 Days	✓		✓	
Vaccines/VFC	✓	+/- 0.5 °C	-50 °C to +8 °C		30 Days		✓		✓
Ultra Low Temp	✓	+/- 0.5 °C	-90 °C to -30 °C		30 Days		✓		✓
Ambient	✓	+/- 0.5 °C +/- 2% RH	0 °C to +70 °C	0% to 100% RH	30 Days	✓		✓	
Extended Temp		+/- 0.75 °C	-200 °C to +75 °C	-20 °C to +200 °C	30 Days		✓		✓
Differential Air Pressure	✓	+/- 0.5 Inch H_2O	-125 Pa to +125 Pa		30 Days		✓	✓	
CO_2	✓	+/- 0.1% CO_2 at 5%	0-20% CO_2		30 Days		✓	✓	
O_2	✓	+/- 0.1% Volume	0-25% O_2		30 Days		✓	✓	

Sensor Storage Data available through CenTrak GDD; 30 days of data. Digital Probes permit plug-n-play NIST recertification.
All sensors are traceable to NIST Standards

Use Cases Served

CenTrak Environmental Use Cases

- BacT - Alert
- Blanket - Saline Warmer dual zone
- Blanket Warmer dual zone
- Blanket Warmer single zone
- Blast Chiller
- Blood Bank dual zone
- Blood Bank single zone
- Blood Platelet with agitator
- Blood Processing
- CO_2 Incubator
- Contrast Warmer dual zone
- Contrast Warmer single zone
- Cryogenic LN_2
- Cryostat
- Deli-Case/Air Curtain
- Dishwasher
- Fluid Bath
- Fluid Bath dual zone
- Freezer
- Freezer dual zone
- Heat Block
- Heat Block dual zone
- Hot Box
- Incubator
- Morgue
- Plasma Thawer
- Pot Washer
- Refrigerator
- Refrigerator dual zone
- Refrigerator/Freezer Combo
- Room Pressure Monitoring
- Room Temp & Humidity
- Transport Cooler
- Transport Cooler with location
- Ultra Low Freezer
- Ultra Low Freezer dual zone
- Vaccine Freezer
- Vaccine Refrigerator
- Vaccine Refrigerator/ Freezer Combo
- Walk - In Freezer
- Walk - In Refrigerator/ Freezer Combo
- Walk-In Refrigerator
- Wax Warmer

NIST-Traceability

CenTrak environmental monitoring measurements are accomplished with specific sensors connected to a wireless interface tag. Sensors and Probes are replaced at scheduled intervals that includes a respective certificate of calibration. For example, temperature probes are certified to be in compliance with EN 60751 Class A and in accordance to ISO 17025 for traceability.

Our probes and sensors are calibrated using standards that are traceable to the National Institute of Standards and Technology (NIST), derived from accepted values of national physical constants or standard reference materials (SRM) and methods. Sensor certifications are typically valid for 2 years in support of CenTrak performance specifications listed in respective product data sheets. Should certifications demonstrate a sensor out of tolerance, the sensor is then recalibrated against the SRM and new calibration parameters are saved to the sensor configuration. Calibration on all probe based sensors from +100 ºC to -40 ºC may be completed by trained hospital staff or certified CenTrak partner. Sensors from -50 ºC to -200 ºC are NIST certified by a trained CenTrak technician. Ambient sensors may be NIST certified by trained hospital staff or certified CenTrak partner.

Best-Practices for Temperature Monitoring

Alerts - A simple mechanism that notifies the user that temperature-sensitive assets are approaching set parameters. The keys to alert structure success are:

- Proper range of minimum and maximum temperatures
- Time delays to avoid nuisance alerts
- Escalation pathways for unresolved alerts
- Clearly defined alert rules

Probe Placement - The temperature in a refrigerator, freezer or warmer can vary throughout the unit. In addition, several external factors can affect the temperature in the storage unit including:

- Placement not centered; too close to a cooling plate or blower
- Comparison of probes that are not collocated in the same buffer
- Improper buffer size for the product being stored
- Too few probes for large cold storage devices; not representative of whole space being monitored

Quarterly Alert Testing & NIST

A typical requirement in critical areas, such as blood banks, is the ability to test the cold storage device at the lower and upper limits of the parameter being monitored. This quarterly alert testing, also known as Fire & Ice, is a comprehensive notification test of the entire system to assure alerts are sent and received at the documented limits.

An added capability is the accuracy certification/calibration of the entire system through the use of comparison of physical standards to an acceptable reference measurement. This is typically completed at the operating condition (e.g., 1 °C – 6 °C) and not across the range of the sensor hardware. In this method, probe and sensor interface are certified as a combined device and assures meeting regulatory requirements set by CAP and referenced in the AABB Technical Manual.

CenTrak Partners and UI Features

CenTrak prides themselves on the ability to enable their partners to integrate the rich set of features available through CenTrak hardware and infrastructure. Below is a comprehensive list of features available through Centrak Partner Solutions.

Environmental Monitoring Features	Description
Single Temp	Measure Temp on Port 1
Dual Temp	Measure Temp on Port 1 & 2 concurrently
Ambient Temp & RH	Can process and present both Temp and Humidity data
Door Ajar	Process open/closed status
Dry Contact	Process open/closed dry-contact status
Local Alert	Send command based LED and Buzzer Alerts to sensor
3rd Party Strobe	Support POE Strobe
GDD	Backfill historical data
Connect Pulse™ API Functionality	Incorporate all CenTrak Connect Pulse API functions
NIST Certificate Support	Pull NIST Certifications and present in UI
Data Intervals (1-60m)	Supports all data intervals, down to 1-min
Automatic button push data	Can process button push to silence UI Alarm
Automatic button push data	Can process button push to accept immediate reading
EM Qualification Process	Has a qualification process aligned with CenTrak for critical departmental needs

Virtual Spares and 24/7 Support

To facilitate rapid hardware swapping and enable 24/7 uptime, CenTrak recommends an added 5% spares inventory of sensors and probes as physical and live inventory. This inventory should be placed in a single location and aptly named the Spares Department. While not actually a department operated under hospital guidelines it is a virtual department. These CenTrak Environmental Sensors are visible through the user interface (UI), maintained by a dedicated staff (e.g., Facilities Management, Operations, Security, etc.), and should be scheduled as part of annual certifications. This dedicated staff must be trained prior to the system Go Live date to troubleshoot and swap hardware, and follow a protocol to update the UI to avoid data loss.

Please ask your local sales representative about this plan.

System Maintenance Agreement (SMA)

CenTrak's Enterprise Locating and Sensing Services™ infrastructure was engineered to be a future-proof platform that grows with your expanding needs. The system has the flexibility to be continually enhanced and upgraded post-installation.

High-quality system support is a key component of our Locating and Sensing Services. CenTrak's Customer Care coupled with our seasoned support engineers are dedicated to providing our customers with technical support and resolving issues before they impact patient care or disrupt clinical workflow.

CenTrak's SMA is composed of the following elements:

Extended Warranty & Technical Support

- Extension of the 12-month warranty on most equipment items for up to eighty-four months provided SMA remains current.
- Access to the CenTrak Technical Assistance Center (TAC). TAC is the main channel for technical support and inquiries. The TAC is staffed by certified technicians and provides timely response to support and service requests.
- Discount on CenTrak battery maintenance and replacement programs.

CenTrak's Connect Core™ Location Platform

Updates, upgrades, new releases, enhancements, and maintenance/patch releases when available:

- CenTrak Location Server: Aggregates tag locations and environmental data from the system
- CenTrak Paging Server: Manages communication to system components
- CenTrak Streaming Server: Streams location and environmental data to specified applications

Maintenance for CenTrak Tags, Sensors and Infrastructure Components

Updates, upgrades, new releases, enhancements, and maintenance/patch releases when available.

CenTrak Connect Pulse™

CenTrak offers a unique solution to remotely monitor the health of all system components to maintain a reliable, high-performance infrastructure. Pulse™ which is part of CenTrak's Connect™ platform offering is part of the SMA program to efficiently monitor and maintain all implementations in one online location, and provides:

- Customizable alerts for defined events to ensure rapid response
- Historic database for analytical resolution
- Reduce downtime by proactively maintaining the system
- Informative reports on hardware performance and status

What is included with the CenTrak SMA?

Updates, upgrades, new releases, enhancements, and maintenance/patch releases for the following system elements:

CenTrak's Connect Core™ Software

- CenTrak Location Server (Aggregates tag locations and environmental data from the system)
- CenTrak Paging Server (Manages communication to system components)
- CenTrak Streaming Server (Streams location and environmental data to specified applications)

CenTrak Tags, Sensors and Infrastructure

- CenTrak Tags and Sensors
- CenTrak Location Monitors and Virtual Walls
- CenTrak Stars
- Other Infrastructure Components

CenTrak Connect Pulse™

- **CenTrak Connect Pulse™** This software is securely hosted by CenTrak and provides enterprise visibility to all system components to enable proactive maintenance and rapid response.

Additional benefits of CenTrak SMA:

- **Access to CenTrak Technical Assistance Center (TAC)** TAC is the main channel for technical support and inquiries. TAC is staffed by CenTrak technical experts and will provide timely response to support and service requests.
- **Extended Warranty** Extension of the warranty on most CenTrak equipment for up to eighty-four months, provided the customer continues to participate in SMA.
- **Discount** on CenTrak battery maintenance and replacement programs.
- **Influence product development** - Ability to influence new versions of the products by posting desired new features and functional improvements.

At CenTrak, we are committed to providing excellent technical support through our knowledgeable staff. Our support staff is available to help answer any questions regarding CenTrak's products. If at any time your team is unable to resolve an issue independently, we recommend that you contact our technical support staff for assistance.

Below is a review of the services and policies that are in place to request technical support from CenTrak.

CenTrak Technical Support

CenTrak has a Technical Support software (CenTrak Technical Support Portal) solution to efficiently manage all technical support requests. Each new request will receive a unique Case Number. You will be provided this Case Number via email to reference for each support request entered. Once a Case Number is assigned, customers may view case history, track status, and/or update the case. This unique Case Number should be referenced for all communications related to the case to ensure you receive the most efficient and effective support from CenTrak staff.

How to Submit a Support Request…

Online

The CenTrak Technical Support Portal serves as the main channel to report technical issues or request support. It connects you to CenTrak's website where you can access useful tools in the Resource Center. The portal will also be used for future enhancements such as our Technical Knowledge Base & FAQ.

To utilize the CenTrak Technical Support Portal and its tracking features, you will need to have an account. Please email supportportal@centrak.com to request an account.

Once you have an account, you can access the CenTrak Support Portal here: https://centrak.force.com/partners/s/.

Note: You may also access this link at any time via the CenTrak website http://www.centrak.com/ by selecting "Support" from the menu listed in the website header or by visiting http://www.centrak.com/support/ directly.

How to Submit a Support Request...

Phone

Technical support is now available weekdays between the hours of 8:00 AM through 6:00 PM in your local time zone, using the following number:

Support Line: 1.215.860.2928 and select option 3 from the menu.

If you are prompted to leave a voice message, please be sure to provide the below information and a member of our technical support team will call you back as soon as possible during regular business hours (Mon-Fri: 8:00 AM through 6:00 PM in your local time zone). Outside of regular business hours, please see our off-hours technical support description.

Leaving a message?

Please provide the following information:

- Your name
- Company name
- Callback phone number
- Email address
- Facility/Site name and location
- CenTrak system and/or equipment involved
- Brief description of the problem or the case number if previously reported

Off-Hours Technical Support

Off-hours technical support requests are typically reserved for critical system failures. General questions and low impact technical support requests will be handled the next business day. Planned off-hour activities should be scheduled at least 1 week in advance when normal business hours cannot accommodate.

Off-hours support should only be submitted via phone.

Response Times and Escalations*

Severity	Description	Weekdays 8am – 6pm in your local time zone	5pm-8:30am & Weekends
1	Critical – Customer is experiencing a network outage that prevents its users from accessing	< 2 Hours	< 2 Hours
2	Major – Customer is experiencing a problem that affects service but business can continue although performance may be degraded.	< 48 Hours	Next Business Day
3	Minor – Customer is experiencing problems that require technical advice or a recommendation for the best solution and have, at most, a slight impact on the operational environment.	< 48 Hours	Next Business Day

*Response & resolution times may be delayed if the site does not have Connect Pulse™ connected or remote access credentials to the server is not available for CenTrak.

For issues that require next level escalation, please contact our Director of Field Service Engineering (Barak Nissan) at BNissan@centrak.com

Fire & Ice Testing

Testing & Certification Processes

CenTrak Environmental Sensors must undergo a Fire & Ice test to ensure sensor accuracy and verify alarm functionality. This evaluation includes the midpoint calibration test, as well as high and low threshold tests. These tests are performed to confirm that sensor specifications are met and that sensors trigger alerts when out of range.

CenTrak Environmental Sensors must not exceed tolerance levels described in the table below during high and low threshold testing:

Temperature Range	Tolerance
-55 °C to -41 °C	0.8 °C
-41°C to -21 °C	0.6 °C
21 °C to -1 °C	0.5 °C
-1 °C to 25 °C	0.4 °C

Testing

Midpoint Calibration Testing evaluates sensors to an accuracy of +/-0.3 °C. The accuracy range is at the midpoint of the sensor temperature range. This is performed by comparing the temperature of the certified NIST thermometer to the temperature of the probe connected to the CenTrak Environmental Sensor in an isopropyl bath maintained at the midpoint temperature. Low and High Temperature Testings are conducted to validate the sensors for operating at the low and high thresholds of the temperature range. Email alerts should occur after raising or lowering the isopropyl bath temperature above or below the threshold range.

Certification

Certification validates and documents that the devices are operational within the temperature thresholds specified by the test design. The CenTrak Engineers that perform the Fire & Ice testing provide a signed certificate to the customer which verifies midpoint accuracy, upper and lower threshold accuracy and successful email alerting. These certifications are valid for up to two years per sensor and probe.

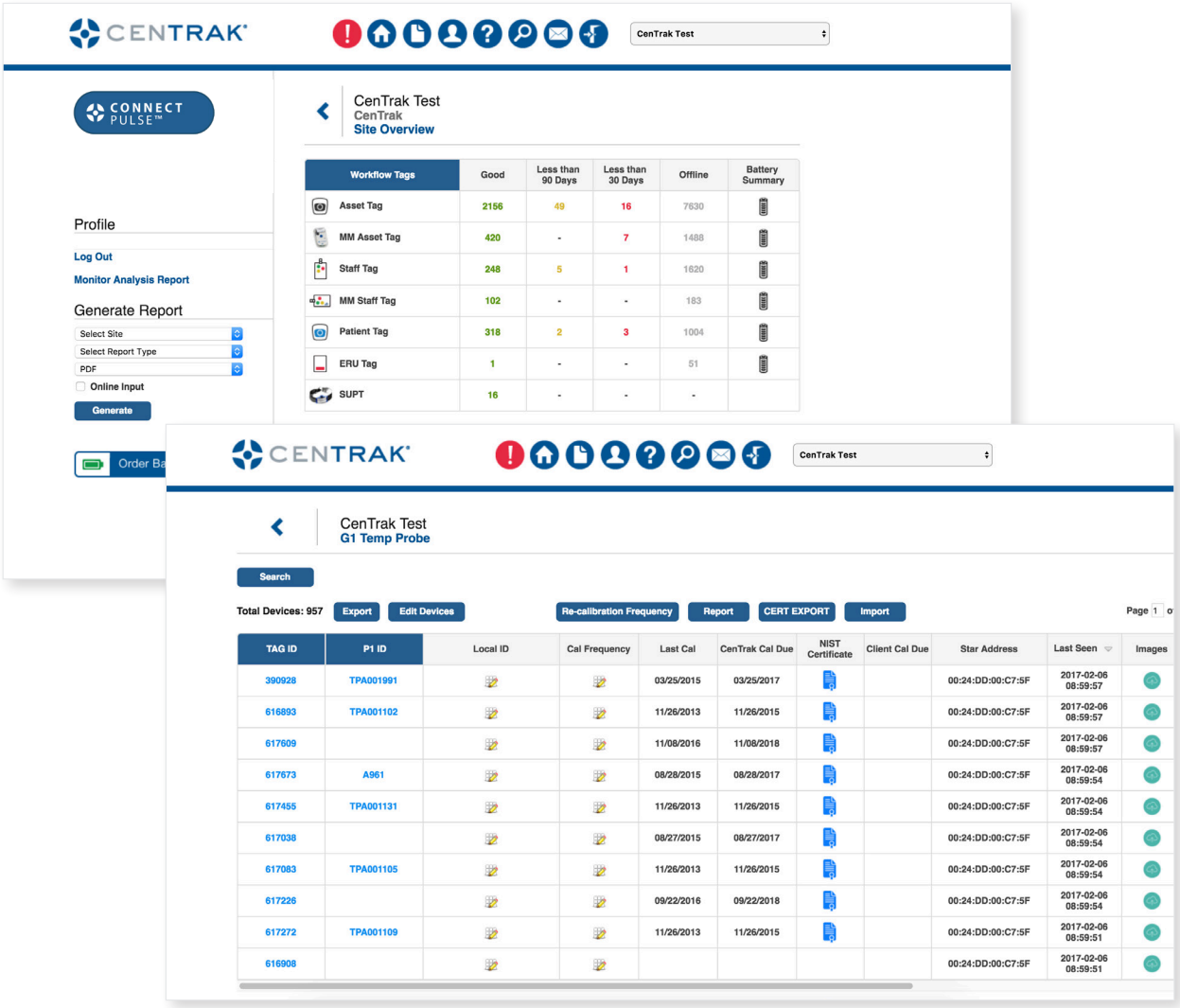
Email marketing@centrak.com to schedule a Fire & Ice demo!

Connect Pulse™ for Environmental Monitoring

Connect Pulse™ provides information about the health of the CenTrak infrastructure for system management. It delivers real-time visibility to devices outside of what can also be generally seen in CenTrak application partner userfaces.

Included in Connect Pulse is the following:

- Infrastructure visibility – know the current status of all network connected devices, IP addresses, and MAC ID's along with whether sensors are online or offline.
- Know battery status of all sensors and when they have 90 days and 30 days left of battery life.
- See all NIST calibration due dates to help in the planning of probe exchanges and assignment of new certificates based on healthcare regulatory requirements.



CenTrak Limited Warranty

The limited warranty period for most supported CenTrak infrastructure (other than consumables) is twelve months. This twelve month limited warranty may be extended for up to eighty-four months, conditioned upon continuous participation in the CenTrak SMA program. The limited warranty on CenTrak proprietary software remains in effect so long as the customer participates in the CenTrak SMA program. Exclusions, and other terms and conditions apply. See your local CenTrak sales representative for complete details.

Contact Us: www.centrak.com | marketing@centrak.com | 800-515-2928