
KELSIUS
Life Sciences
Wholesale & Logistics
Digital Wireless
Temperature Monitoring Solutions

KELSIUS

Company Story

Kelsius are Ireland's only manufacturer and provider of Wireless Temperature Monitoring and Digital Task Management systems and we take pride in being a Guaranteed Irish company.

Founded in 2003, Kelsius is a technology company that has a strong market presence in Ireland and the UK and exports their products and services to 47 countries across the globe.

Our customers range from pharmaceutical manufacturers, hospital pharmacies, laboratories and blood science departments, life science facilities and vaccination centres.

We are committed to continuous innovation and our systems utilise the latest technologies to provide peace of mind and easy-to-use systems to our customers.

Our customer support team offer unrivalled levels of service and can offer 365/24/7 support when required to global customers.

Our Mission:
To make the world safer for consumers of food and medicine.

ISO9001:2015 Accredited

ISO14001:2015 Accredited

ISO 27001 compliance through our partners AWS

Kelsius system complies with FDA 21 CFR Part 11 regulations

Sustainability

Our Commitment

We are committed to improving global sustainability by focusing on four principles.

Remove
Paper

Reduce
Waste

Protect
Stock

Save
Energy

EcoVadis – Sustainability Silver Medal Certificate

Kelsius has been rated amongst the top 25% of global companies assessed by EcoVadis. The rating was achieved based on EcoVadis' evidence-based assessment of Kelsius in relation to its sustainability impacts.

Our Solutions

Reduce Waste

Every year, billions of tonnes of waste directly contribute to generating high levels of greenhouse gas emission. The vast majority of this waste is due to lack of cold chain traceability or incorrect storage temperatures. Reliable temperature monitoring ensures storage units and products are consistently kept at optimal temperatures, removing the risk of stock being spoiled. This prevents large amounts of unnecessary waste.

Reduce Paper Usage, Paper Waste and Paper Storage

The average small-medium business must have on average 10,000 sheets of paper available annually to conduct manual temperature monitoring, with each sheet taking 6-9 years to decompose. Our systems remove the need for manual paper records therefore significantly reducing a company's paper and ink cartridge waste.

Save Energy

As well as using water, chemicals, plants and other resources in production processes, products that end up as waste each year also use significant amounts of energy. By reducing the amount of waste, the Kelsius system ensures that this energy does not go to waste. The temperature monitoring system also allows for constant monitoring of systems, allowing you to ensure that temperatures are set at optimum levels and that your units are operating at the most efficient energy levels.

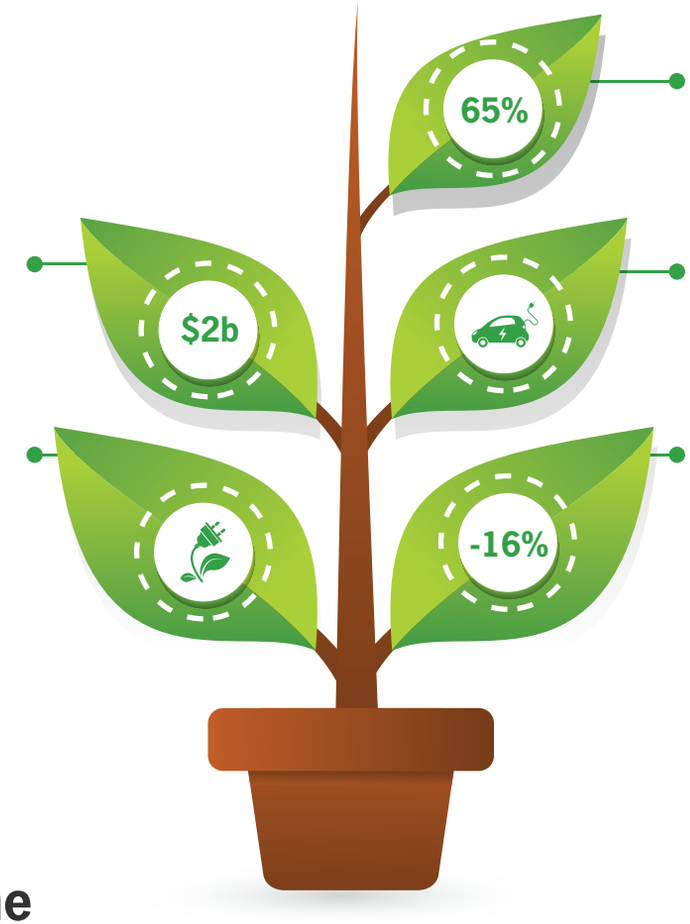
Our Contribution

Our contribution and responsibility is to reduce emissions and environmental impact across our operations.

With the requirement to maintain records for up to 30 years, data storage is a large and important part of our business. We chose Amazon Web Services (AWS) as data storage partner as a result of AWS' focus on Sustainability.

AWS created The Climate Pledge Fund, a $2 billion investment to support the development of technologies and services that reduce carbon emissions

AWS is the world's largest corporate purchaser of renewable energy



AWS reached 65% renewable energy across the business in 2020 (up from 42% in 2019).

Following AWS order of 100,000 electric vehicles from Rivian in 2019, they rolled out the first of these vehicles in Los Angeles in February 2021

AWS decreased their overall carbon intensity by 16% from 2019 to 2020

Plant a Tree Programme

Reducing global paper usage and waste is one of our main objectives as a company and to enhance this, we have decided to plant a tree for every new customer that comes on board. Trees remove carbon dioxide from the atmosphere, produce oxygen and support the building of biodiversity, so together we will be directly contributing to improving the environment.

Security

Security & Compliance with Kelsius

Your Data and Privacy are Protected and Secured

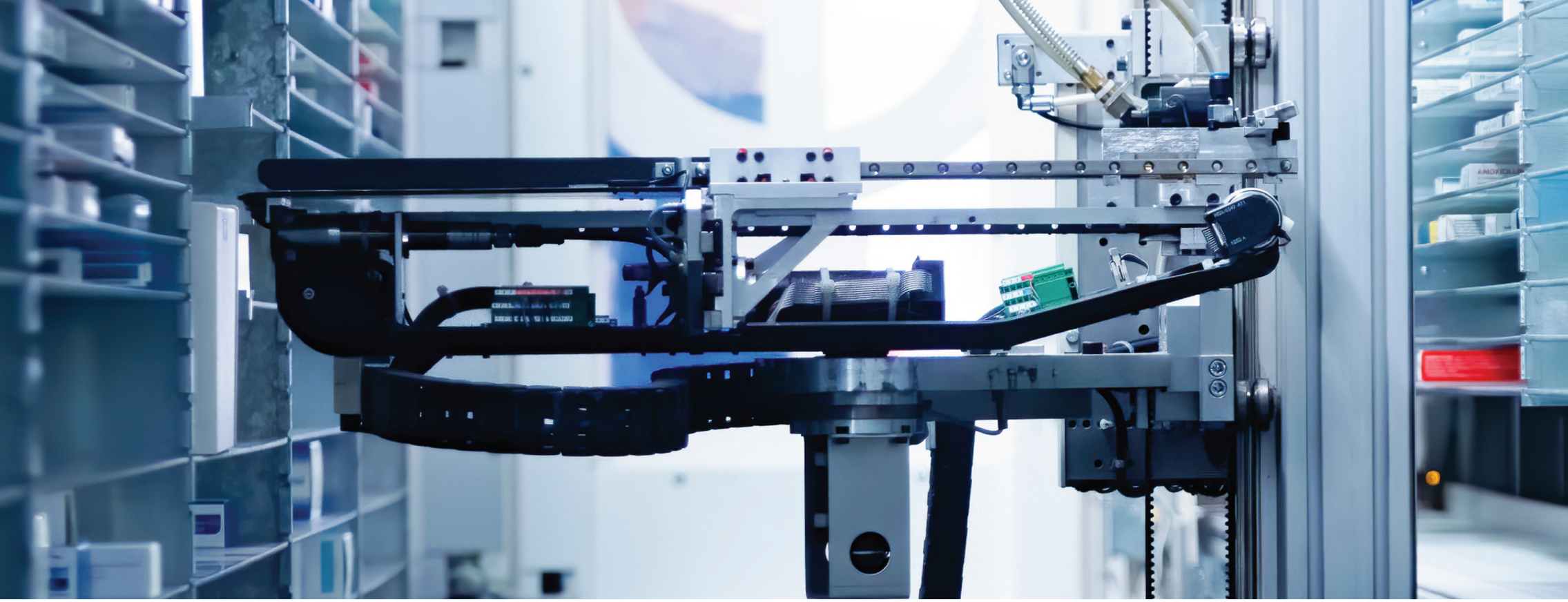
Kelsius develop secure software design practices that include defining security requirements, threat modelling, code reviews, vulnerability management, incident resolution management and security testing. There are controls in place to validate/reject access to the customer portals including multi-factor authentication, roles and permissions.

- GDPR Compliant
- Data processed and stored in the EU
- Data encrypted at rest (data storage) and in transit (data transfer)

Information is readily available

Daily and incremental backups allow data to be restored to any 5-minute period between backups. Data archived for more than 13 months can be restored from the portal at any time for audits of historical data and there is data retention for 30+ years. There's also an automated disaster recovery plan in place to ensure maximum uptime across 3 geographically dispersed data centre locations within Ireland.

- 24/7/365
- Alerts via push notifications/email/voice calls/SMS
- Self-healing data storage
- Automated crash recovery over multiple data centres



You are compliant

Kelsius complies with FDA 21 CFR Part 11 regulations – ISO 27001 compliance (AWS). A complete audit trail is available including user activity and change management audit records. There are multiple user roles to customise and control access to data and system configurations, and strong data governance where data is only accessible by the customer and a controlled small number of Kelsius employees.

Complete manufacturer IQ/OQ documentation is available for both software and hardware, and optional on-site validation.

Strong password policy is enforced and multifactor authentication is used to access the customer portal.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Wireless Repeater
DO NOT UNPLUG
INPUT 12VDC 50 Hr Battery Backu
KELSIUS
Thermocouple
Temperature Sensor
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KELSIUS
Wireless Alarm
www.kelsius.com
KELSIUS
Wireless Temperature Sensor
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Wireless
Temperature Sensor
I-O

Industry Challenges

- To maintain quality in life sciences and healthcare supply chains, it is critical that proper temperatures are maintained whether products are stationary or in transit.
- Quality and compliance break down when cold chain management breaks down.
- Temperature excursions can occur for a wide variety of reasons.
- Operator error, refrigeration equipment malfunction, poor quality insulated packaging, vehicle breakdown, or poorly managed delivery and loading practices are just some of the potential points where failure can occur.
- Undetected fridge/freezers breaking down or doors left open can lead to substantial loss of valuable products.
- Manual temperature and humidity records can be difficult to manage and are open to human error.
- Missing records can lead to audit failure.
- Maintaining paper records is time-consuming for management and staff, requires storage space, and incurs costs for paper, printing and ink cartridges.

The Solution

The CoolCheck wireless monitoring system automates monitoring of temperature and humidity in controlled environments. CoolTrack sensors continue to protect products in transit. The systems protect products in environments such as pharmaceutical manufacturing and packaging, laboratories, hospital laboratories, blood banks, clinical pharmacies, retail pharmacies, incubators, wholesalers, distributors, and logistics service provider operations.

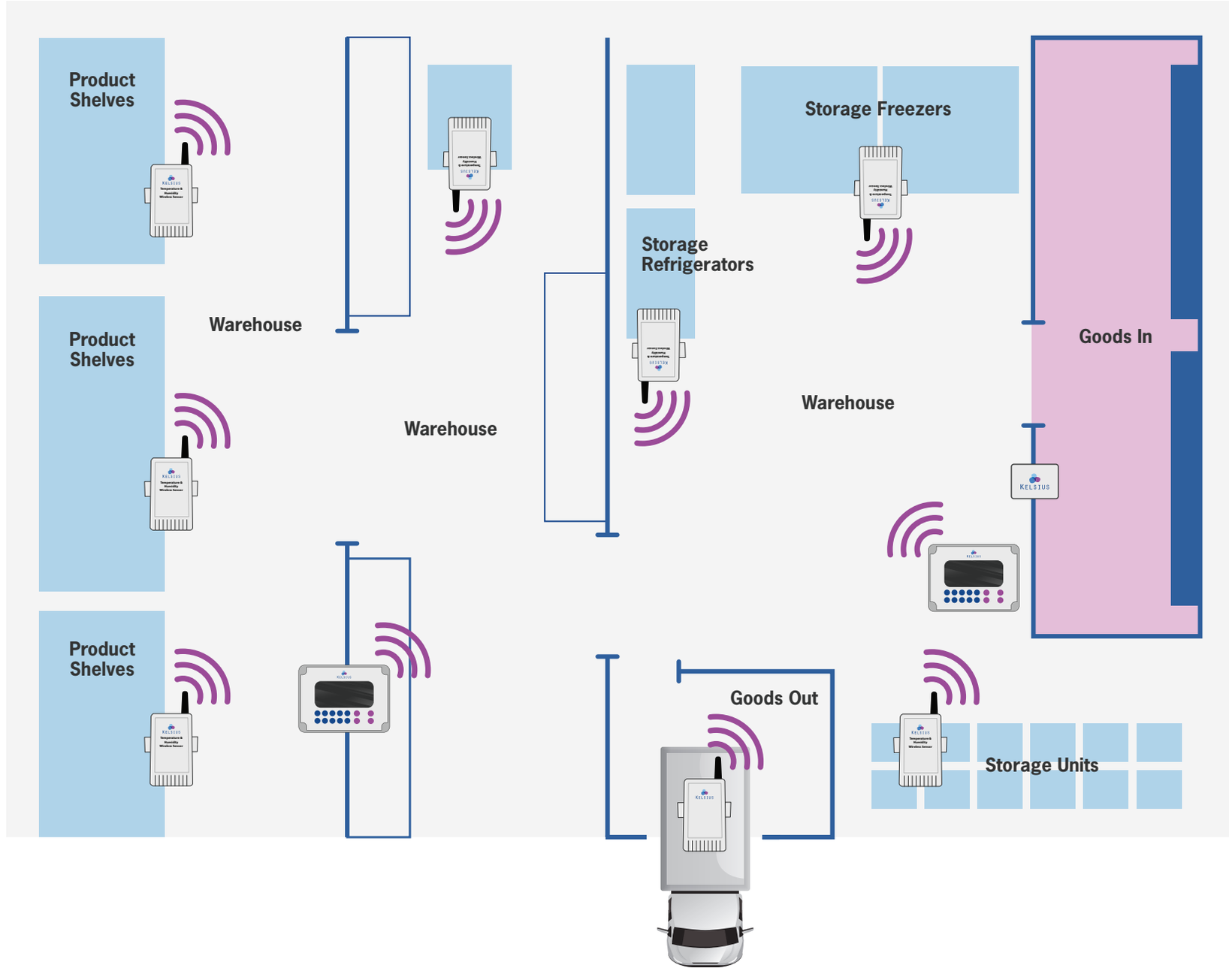
- The stationary and mobile monitoring systems ranging from -200ºC to +50ºC keep you in compliance to meet global regulations, Good Manufacturing Practice and Good Distribution Practices.
- Stationary and mobile wireless sensor network supports monitoring of large and small controlled and in-transit environments.
- Real-time reporting gives managers visibility of all task completion, records, non-conformances and corrective actions as they happen.
- The systems close any gaps in cold chain traceability, reducing waste or loss and associated costs.
- Live and historical data is available on the Kelsius Web Portal from any web-enabled device, while automated PDF reporting helps you to maintain quality control, safety and operational efficiencies.
- CoolCheck–ed ✓ app eliminates all paper from your daily operations removing the cost of paper, printing, ink cartridges, paper record storage and time spent on paperwork.
- Automated sensors record temperatures every five minutes, eliminating the need for manual temperature recording and the associated risks of human error. Record-keeping data is secure and time/date stamped.
- 24/7 automated SMS, email or telephone call alerts warn key staff members of temperature excursions, power outages or doors left open, avoiding any loss of stock or disruption to operations.
- Push notifications are an alternative to automated SMS or voice call alerts, which mobile network providers increasingly treat as spam resulting in non-delivery. Push notification alerts provide maximum security and reliability, with the most robust encryption protocols in place to protect sensitive data. Two-factor authentication provides users with an additional layer of security. The app also provides secure remote functionality, delivery confirmation and delivers notifications even when the recipient is offline.
- Key members of staff are freed up to concentrate on other activities, increasing staff productivity.
- A full range of calibration services is provided as required.

The CoolCheck Temperature Monitoring System:

- 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 checks and records.
- Secure, centralised, encrypted data keeps your records safe.
- 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.

Lifetime Warranty

Eliminate system redundancy and end of life re-purchase costs. All Kelsius manufactured equipment including sensors, repeaters and network controllers come with a lifetime warranty during the term of your agreement. Items will be replaced with like-for-like or an upgraded version where an older part has been made redundant. New parts are manufactured to be backwards compatible with the existing system and software.


Product Shelves
Product Shelves
Product Shelves
Warehouse
Warehouse
Storage Freezers
Storage Refrigerators
Warehouse
Goods In
Goods Out
Storage Units
Wireless Temperature Sensor
CoolTrack Sensor
Network Controller
Cool Track Docking Station

CoolCheck Monitoring System at work:

CoolCheck is a fully integrated solution for facility temperature, humidity and condition monitoring which combines wireless sensors which are linked to their own network and web portal.

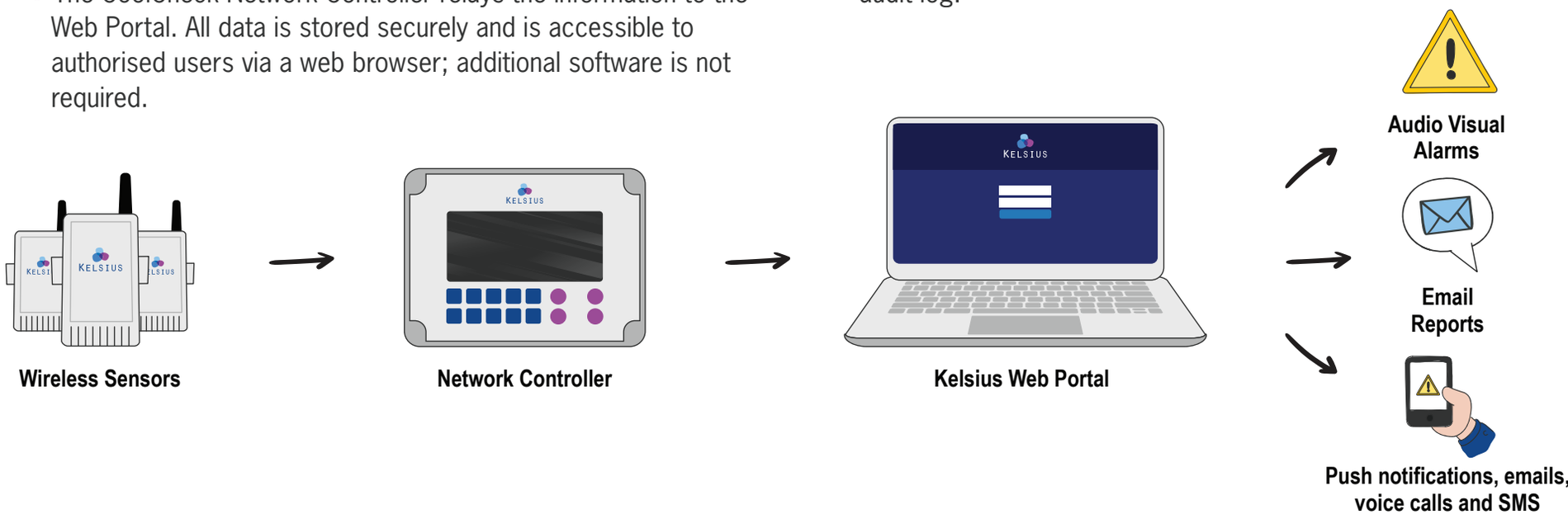
CoolCheck wireless sensors are configured with user-defined alarm thresholds and measurement intervals. They are strategically placed inside any number of storage areas to record environmental conditions.

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

- The CoolCheck Network Controller relays the information to the Web Portal. All data is stored securely and is accessible to authorised users via a web browser; additional software is not required.

- The CoolCheck Web Portal provides immediate access to real-time and historical sensor data for all monitoring locations—and accessible from any web enabled device. Reports are available on demand or can be scheduled using a report wizard which will generate and distribute reports automatically via e-mail.

- When an excursion occurs, designated personnel can be alerted through audible/visual alarms, or automated app push notifications, emails, automated voice calls or SMS. Once a problem has been identified and corrective action has taken place, the incident can be recorded in the system's historical audit log.



Push Notification Alerts

Push notifications are a secure and reliable alternative to SMS or voice call alerts. Mobile phone network operators are increasingly treating automated SMS and automated voice calls as spam. This can result in the non-delivery of messages and in turn risks the user not receiving critical alerts of temperature excursions that could affect products, specimens or samples.

Push notifications are delivered via the Kelsius App and have multiple benefits for healthcare professionals:

- **Encryption and Security:** The app uses more robust encryption protocols, providing a secure way to transmit information. This is particularly crucial for sensitive notifications affecting patient safety and high-value pharmaceutical products. This ensures that messages are less susceptible to interception, being isolated or not delivered, and are delivered in a reliable, consistent and dependable manner.

- **Two-Factor Authentication (2FA):** The app supports two-factor authentication, adding an extra layer of security. Users can receive secure authentication codes directly through the app, enhancing the overall security of the communication.

- **Delivery Confirmation:** The app provides delivery confirmation, letting users know when a message has been successfully delivered and when it has been read. This feature enhances reliability and helps users ensure that their messages reach the intended recipients.

- **Offline Message Delivery:** Push notifications are designed to be more reliable in delivering messages even when the recipient is offline. In addition, the app can store notifications until the user is back online, ensuring that important messages are not missed.

- **Remote Functionality:** Remote features include:

  - Secure login from any mobile device
  - Ability to select any individual alert event by entering a PIN
  - Ability to enter a predefined or custom corrective action
  - Ability to close the alert event without going back to office or a central location
  - App will report if alert notification was delivered, if it was opened and if it was actioned
  - All actions recorded and viewed on portal audit section
  - Provides improved traceability, convenience and saves time

Data at your Fingertips

The CoolCheck 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 organisation 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.

Humidity					
Sensor Name	Min.(%)	Max.(%)	Average(%)	Standard Deviation	Total Records
Sensor 1 (Basement)	41.5	53.3	45.4	3.3	293
Sensor 2 (Basement)	42.0	53.8	45.9	3.1	293
Sensor 3 (Warehouse - Basement)	41.3	53.1	45.3	3.0	293
Sensor 4 (Warehouse - Basement)	41.0	53.3	45.2	3.4	292
Sensor 5 (Warehouse - Basement)	42.0	53.7	46.0	3.1	293
Sensor 6 (Warehouse - Basement)	42	53.1	46	3.1	293

Secure Data, Real-Time Alerts

Alarming and alerting capabilities are key features of the CoolCheck system. The system 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:

- Audible/visual alarm beacons can be installed at various high-visibility points 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.

- Push notifications, emails and SMS can be configured to reach designated personnel and provide delivery confirmation, with messages including the exact location and details of the alarm.

- Escalating alerts can be made to designated personnel via automated out-of-hours voice calls until someone logs in, investigates the alarm, and takes action.

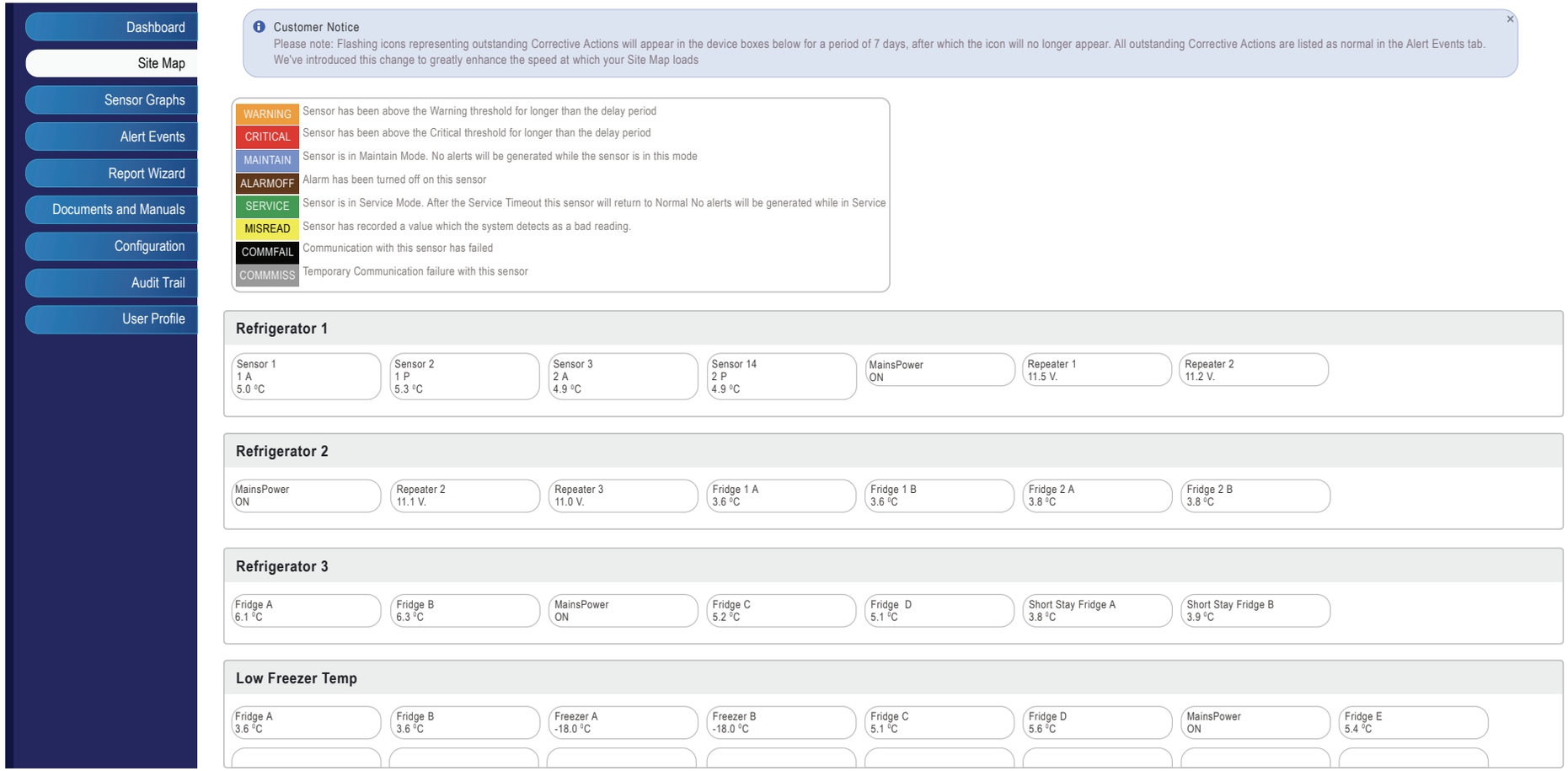
Corrective actions can be used to document your process controls. Once an excursion has occurred, corrective actions can be entered by authorised users. A user can select from a pre-defined list or can manually enter a corrective action. Every corrective action is date and time stamped and includes electronic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

In addition, all data transmissions are encrypted for security assurance.

Electronic record keeping ensures a robust audit trail. The CoolCheck system 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.

Your Data: Secure & at Your Fingertips



CoolCheck Technical Specification

CoolCheck Wireless Sensor Specification			
	Temperature	**Temperature and Humidity**	**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)
Frequency Bands	868 or 915MHz	868 or 915MHz	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)	-35°C to +40°C (-31°F to +104°F)
Temperature Accuracy	0.2°C (+ 0.9°F)	±1.0°C (±1.8°F) [Range 0°C to +5°C (+32°F to +41°F)] ±0.2°C (±0.9°F) [Range +5°C to +50°C (+41°F to +122°F)]	+ 0.2°C (+ 0.9°F)
Temperature Resolution	0.3°C	0.1°C	0.3°C
Humidity Range	—	10% to 90%, non-condensing	—
Humidity Accuracy*	—	*+5%* **RH Accuracy stated within Temperature Exposure Range of: 5°C to +50°C, Non-Condensing*	—
Humidity Resolution	—	0.1%RH	—
Data Storage	5,461 data points	5,461 data points	5,461 data points
Battery Life	5 years	5 years	5 years
Battery Type	Lithium TiCl 3.6V 2Ahr	Lithium TiCl 3.6V 2Ahr	Lithium TiCl 3.6V 2Ahr
Configurable Measurement Interval	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	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))	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)	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

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

KELSIUS

kelsius.com

Email sales@kelsius.com
Web www.kelsius.com
Call 074 91 62982

Kelsius Ireland
Unit 2 Ballyconnell Industrial Estate
Falcarragh
Co. Donegal
Ireland