

Continuous Temperature Monitoring for Compliance



The Pennine Acute Hospitals NHS Trust serves the communities of North Manchester, Bury, Rochdale and Oldham, along with the surrounding towns and villages and has a population of around 820,000.

The Trust provides diagnostic pathology services at the central laboratory at the Royal Oldham Hospital and satellite laboratories at Fairfield General and North Manchester General Hospitals. In addition, satellite blood fridges are in use at these sites and at Rochdale Infirmary.

The Trust provides two major emergency-receiving hospitals at North Manchester and The Royal Oldham; The Royal Oldham is also a designated trauma centre. This is supported by emergency medical and elective surgery services at Fairfield General and an Urgent Care Centre and Clinical Assessment Unit at Rochdale Infirmary.



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The Monitoring Need

Compliance to EU transfusion guidelines drives the monitoring need at this busy healthcare NHS Trust and rigorous temperature monitoring to ISO15189 standards is mandated in this project for pathology labs, predominantly blood products across multiple locations and remote laboratories in the estate. This included:

- Haematology and Blood Transfusion
- Biochemistry
- Microbiology
- Cellular Pathology
- Mortuary
- Andrology

While the refrigeration units had built in monitoring that met MHRA standards, they failed to provide the granularity of information required about monitored inventory and temperature variances.

The Trust researched the market for a temperature monitoring system that would meet compliance requirements of ISO 15189, but also provide the rich data and presentation specified by their expert users.

The search began a for a system that would meet these particular specifications, paired with a cost that was manageable as they also required 24/7 alarm coverage with real-time alarms to resolve excursions prior to the pre-set time limits for a number of monitored units.

The Tutela Monitoring Solution

Although the existing system in place could be extended, the Pennine Acute Trust found a better solution in Tutela's temperature monitoring system, which delivered greater functionality, greater integration at a cost that met the Trust's budget parameters.

The installation required 4 WARP units, fed by 126 temperature sensors (chilled, ambient and humidity) driving a fully interactive web-dashboard. The intuitive web-based interface allows users to gain access to, review and download their private sensing probe and incident audit records and provides vital real time data.

Being web based, the Tutela system meets the highest level of record security to its customers being fully compliant with FDA CFR 21 part 11, and allows comprehensive access to customer data at anytime, anywhere through the use of Smartphone, Tablet or Laptop or any device able to support a web browser.

Installation required minimal involvement of IT resources and Tutela set up a webinar training session broadcast to 300 users to enable rapid operation. The system was calibrated to ISO17025 by Tutela engineers.

Key points

- Remote alarming by real people is crucial for maximum inventory protection
- On-line operation allows remote activation and assessment
- Secure web access to the user interface allows isolated units to be addressed
- Specialist providers offer more focussed solutions
- The importance of a calibrated system to meet MHRA compliance

“The Tutela hardware and connectivity was robust, and the brand has a good reputation within the blood industry. Importantly it's a very user-friendly system”.

Michael Heaton – Haematology and Blood Transfusion Service Lead | [Pennine Acute Trust](#)

