

R&D Laboratory Tutela Temperature Monitoring System

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

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This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	14 th September 2018	

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1.0 Introduction, Background and Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the correct use of 'Tutela' – Laboratory Medicines new temperature monitoring system.

This SOP details the processes in place for temperature monitoring and control of storage areas for clinical research samples, reagents and consumables. Samples taken as part of a clinical research project can often be stored locally for significant periods of time prior to being shipped to central labs for analysis/ or being analysed locally. The storage conditions in which samples should be maintained must be identified at the study set up (in study protocols/laboratory manuals or associated study documentation/ or written confirmation from the study sponsor). Records detailing where and how long research samples were stored for each individual study prior to shipping and/or analysis are maintained within the study Laboratory File (full chain of custody of research samples at York Trust sites).

Ongoing monitoring of refrigerators and freezers used to store research samples will be conducted using 'Tutela' system to identify and maintain complete record of temperature records and any temperature excursions. The Tutela monitoring system has been installed as it provides a fully validated, compliant and calibrated to UKAS standards data recording and monitoring system for all scientific facilities that store sensitive inventory. It is a site-wide cloud-based monitoring system with remote alarming which provides a solution for our temperature control compliance and safeguarding needs.

The system provides complete record of temperature monitoring, including record of actions taken in the event of a temperature excursion (an online alarm incident facility). A combination of devices (Thermometer Probes and Transmitters) are used to record the temperature and transmit the data wirelessly to a central hub. The Hub synchronizes local data with the central web application. Effectively all temperature records are stored centrally and historical data is available online indefinitely. Temperature data is recorded at 5 minute intervals and is available 24/7. Temperature status may be viewed on the Hub however more detailed information may be taken from the centralized temperature control system available on the website.

The Tutela online alarm incident handling facility allows users to create and manage alarm incidents remotely. This records the cause of the incident, the action being taken to resolve the incident and also records the resolution of the incident. Tutela will alert for the York Site via the R&D call list of any breach in temperature control outside pre-determined limits.

This SOP details an overview of the Tutela website, the action to be taken if an incident alarm is raised by Tutela, how to manage isolations and how temperatures are monitored on the Tutela system. The system has been introduced to streamline temperature monitoring within Laboratory Medicine and R&D. The main improvements that will arise from Tutela are:

- Automatically recorded temperature readings
- Consistent weekend monitoring

- Remotely accessible monitoring platform
- Accountability for investigating alarm causes and prevention of such alarms.
- Complete record of temperature deviation allowing clear oversight of their extent/frequency and any patterns of repetition
- Reduction of paper files and associated time in maintaining such files.

2.0 Who Should Use This SOP

This SOP is aimed at the following people:

- R&D Laboratory Staff
- Emergency out of hours nominated R&D Staff.
- Research Teams who wish to monitor the performance of Fridges & Freezers.

3.0 When this SOP should be used

- For general day to day performance monitoring of R&D Fridges & Freezers
- For guidance in out of hours alarmed situations for nominated R&D Staff.

4.0 Procedure(s)

4.1 Overview of the system

TUTELA System is installed for Temperature Control across both sites York & Scarborough.

The Tutela website is accessed using the following link:

<https://v4.tutelasystems.com/main/login>

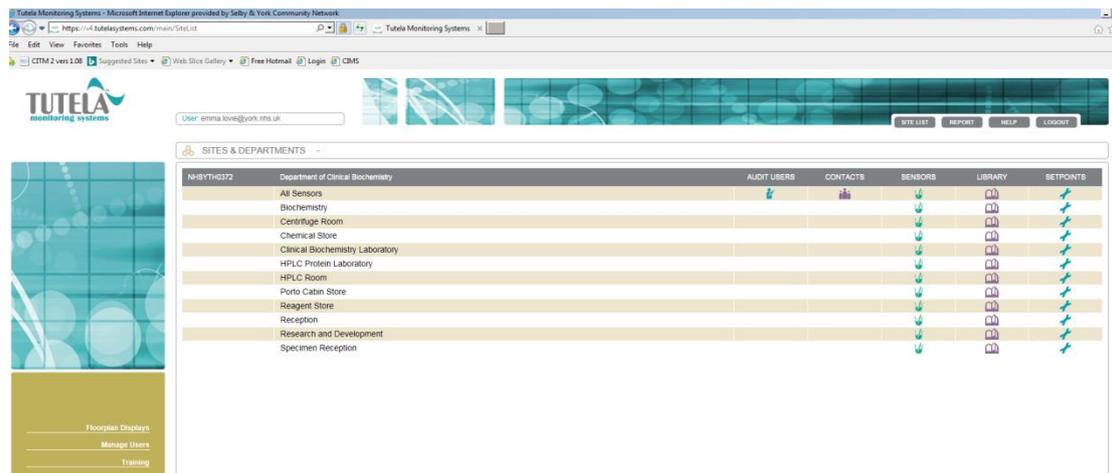


The screenshot displays the Tutela Systems website interface. On the left, there is a login form with fields for 'User Name' and 'Password', a 'Login' button, and links for 'Reset Password' and 'Reset Pin Code'. The main content area is divided into three sections: 'HOW TO CONTACT US' with contact details for Europe and North America, and 'WEB SITE SERVICE STATUS' with a notice about website availability and a recommendation to contact customer support for help.

- Log into the system by entering your user name (this is your work email address) and your password.

- If this is the first time you are logging onto the system, you will need to accept the terms and conditions on the screen that is displayed. You will also be required to reset your password in the webpages that follow. You will also need to reset you PIN code. This acts as an electronic signature when dealing with incidents. To reset your PIN code, from the log in screen select 'Reset Pin Code'. Enter your username (email address) and email address and press send. You will receive an email with a randomly generated 9 digit PIN number.

You will now be on the main home screen



The main home screen displays a list of all the sensors per room situated in the Biochemistry/R&D department.

Audit Users

This shows the activity on the website by each user.

Contacts

This is where the contact list for who is called and when can be found.

Sensors

By clicking on the sensors icon, it will display a list of sensors in that room, along with the current value and options to view graphs and tables and manage incidents and isolations.

Library

This is where the Tutela user manual and maintenance documents are kept.

Set points

By clicking on the set points icon, will display the high and low alarm points for each sensor. It will also display the delay time before an alarm will be triggered.

Sensors

After selecting the sensor icon, it will open up a new screen

CHANNEL	DESCRIPTION	VALUES	GRAPHS	TABLE	INCIDENT	ISOLATIONS	BATTERY
2006A	T01287 Double Fridge	6.4 °C					
2007A	Lab Ambient (Biochemistry)	27.2 °C					

- It will display the most current recorded value.
- By selecting the graph icon it will display a graph of the day's temperature. Previous day's data can be viewed by using the arrows on the left hand side menu.
- By selecting the table icon, it will display a table of all the recorded temperatures taken that day, including the Min, max and average for the day. More data can be viewed by using the arrows on the left hand side menu.
- By selecting the Incident icon it will display a list of any incidents on the sensor.
- Selecting the Isolations icon will allow you to view if a sensor is in isolation (If you have permission, you can manage isolations for this sensor).

4.2 Performing Daily Temperature Checks

To ensure the Tutela monitoring system is performing correctly a 'Check Readings' should be performed daily for both 'York - R&D' and 'Scarborough Porto Cabin Store 2013A'

Click on a sensor icon (or to check the full system, select all sensors), and select 'Check Readings' from the left hand menu. This will take the temperature from every probe and display the results on screen.

Additionally, at times when any research samples are stored at Scarborough Labs, 'view incidents' for Scarborough sensors should be performed on daily basis and recorded on the 'Laboratory QA checklist'. As the alarm incidents are handled by Scarborough Laboratory staff (as specified in section 4.4), this check ensures that the incidents reported for fridge/freezers used for storing research samples are assessed by the R&D Associate Practitioners and appropriate actions taken as required (check the incident report, ask for further details if needed and ensure the impact on samples' integrity is assessed and the sponsor is notified if required).

4.3 Action to be taken if temperature falls outside predefined temperature range

If an incident alarm is generated by Tutela corrective action should be taken. If during routine working hours, R&D Associate Practitioners are expected to accept and clear the incident via Tutela (see section 4.5 for details)

Log onto Tutela and click on the flashing RED Sensor alarm across from York – R&D. This will then take you to screen listing equipment. From here you can see information about the incident. You should pay close attention to viewing the 'graph' section to see the current and previous trend of the temperature.

Actions towards bringing the temperature back into range in can include some or all of the following:

- Checking the door to the fridge/freezer/incubator has not been left open
- Recording an explanation e.g. stock check, reagent delivery stored away

- Adjusting the thermostat control
- Defrosting the freezer to ensure it can work efficiently
- Contact facilities to request an engineer
- Remove contents of the fridge/freezer to an alternative location to ensure the contents are kept at the required temperature.
- Ultimately, have the device in question condemned and replaced if necessary.
- Adjusting (if necessary) the air conditioning to control room temperature after discussing the change with a section senior in Biochemistry.

If the incident occurs out of hours please refer to Appendix A.

4.4 Managing Incidents

Tutela has an online alarm incident handling feature which creates and manages alarm incident records online.

On receipt of an exception alarm from either the York or Scarborough site an incident audit form is automatically generated on the website. There are 4 stages to handling a reported alarm incident:

- Identify the cause of the problem
- Take appropriate action to resolve the problem
- Validate that the problem has been resolved
- Verify the resolution process and sign off on the incident.

For York Site: Tutela will call the laboratory to notify R&D Staff that an exception alarm has occurred in the following order:

01904 725887 R&D Office
07789 174492 R&D Mobile

Temperature excursions that self-resolve within 10 minutes will not generate an alarm. Research & Development have concluded that temperature excursions to this degree will not affect sample integrity.

For Scarborough Site:

There will be no out of hours call list for Scarborough Site relating to R&D staff. Scarborough alarms will be dealt with via the Scarborough Biochemistry out of hours call list.

It is the responsibility of R&D Associate Practitioners to monitor the performance of research sample containing equipment at Scarborough daily as part of The Laboratory QA Checklist.

Equipment that currently stores trial samples at SGH are as follows:

- Main Porto Cabin Store – Channel 2013A

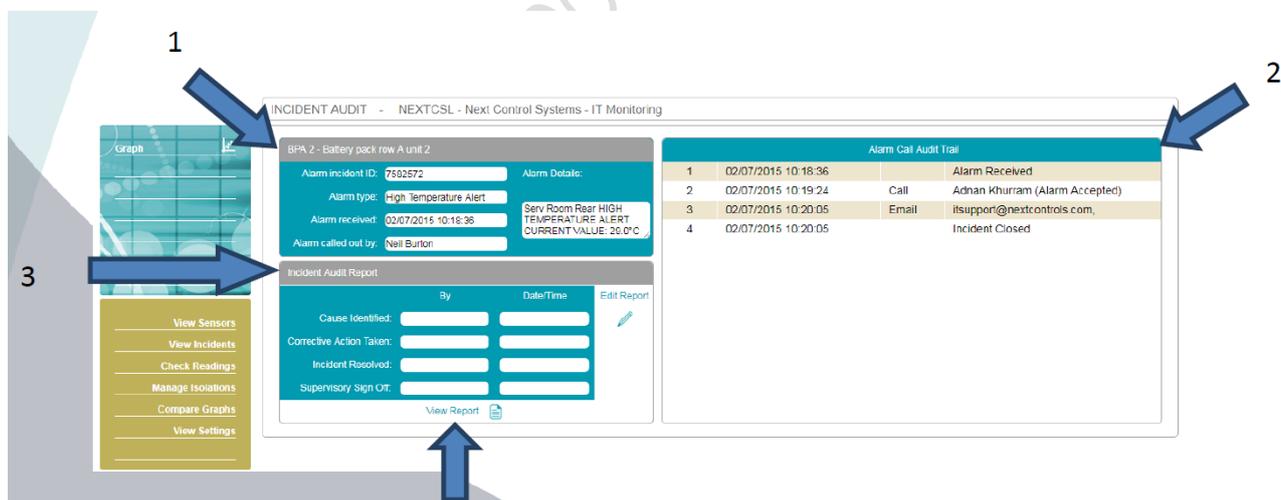
To action an exception alarm:

- Log onto the Tutela website
- Identify the alarm on the system. On the home screen, the sensor with the alarm will be displayed in red. Click on the red sensor icon to open the list of incidents that are pending.

SITES & DEPARTMENTS - Next Control Systems

NEXTCSL	Next Control Systems - IT Monitoring	AUDIT USERS	CONTACTS	SENSORS	LIBRARY	SETPOINTS
	All Assets					
	Assetgrp2					
	sean test					

- Click on the Incident icon. This will direct you to the Incident Audit screen.
- On the Incident Audit screen, there are 3 boxes containing information regarding the incident:
 1. This is a summary of the incident that has occurred. Information includes the type of alarm, the date/time of alarm and a summary of occurrence. Each incident is also assigned an Incident Audit ID.
 2. Alarm Call Audit Trail. This box contains the order of operations followed by Tutela once an alarm has been triggered.
 3. Incident Audit Report. Each line needs to be completed to clear the alarm. After the first line is populated, the audit icon will change from red to orange. After the fourth line is completed, the audit icon will go back to green.



- Identify the cause of the problem and enter it into the 'Cause Identified' box.
- Enter the action taken to resolve the problem in the 'Corrective action taken' box. Add information regarding the extent and duration of the temperature excursion the research sample(s) were subjected to, and an assessment of the impact of the excursion on the sample(s) integrity.

- Once the incident has been resolved, enter your name into the 'Incident Resolved' box
- A Research & Development Associate Practitioner will then sign off the incident.

A full report of the incident can be viewed by selecting 'View report' icon found under the Incident Audit Report Box

A list of all incidents, open, pending and closed can be found by clicking the 'View Incidents link' on the left-hand side of the home screen. This will bring you to the Site Incident History.

4.5 Managing Isolations

Please make sure to put sensors in isolation (inactivating the alarm) when required to avoid unnecessary phone calls from Tutela, for example when defrosting a freezer or when placing stock/samples in/out of fridge/freezer with the door opened for extended period of time.

To put a sensor in isolation:

- Find the correct sensor from the sensor list
- Select 'Manage Isolations' from the left hand side menu
- Isolation status red  represents that alarm is currently inactive for this sensor
- Select the 'View' button if any isolation exists for this sensor.
- Select 'Add' to add an isolation to this sensor. This will bring up a pop-up box. Put the start and end date and time and select isolation type i.e. once or weekly. Select 'Save'.
- Selecting the 'view' button in the last column of the sensor list page will present the user with all the isolations for this sensor.
- An isolation can be disabled by pressing the 'disable' button  and details can be viewed by pressing the view button. 

4.6 Monthly Monitoring of Temperature Records

A monthly report will be performed to review the average temperature of all fridges/freezers and room temperatures to identify any trends/issues or if any corrective action needs to be taken (e.g. defrosting of a freezer).

The number of incidents received will also be reviewed on monthly basis. . Incident Report for York- R&D & relevant Scarborough sensors will be generated & reviewed for any patterns of repetition and clear oversight of their extent and frequency, and for escalating issues to R&D as necessary.

These quality control checks will be analyzed and the reports saved electronically into the documents library in York – R&D Tutela Library, and noted on the 'Laboratory QA checklist'

4.7 Reports

Reports can be produced from the website which displays data from the sensors or incident reports.

To create a report log in and access the home page – then select York – R&D by clicking on the icon under ‘sensors’ across from York – R&D. Then click on the piece of equipment you wish to report by selecting the icon under graphs.

Click on the calendar icon (top left blue box) and from here, select the ‘start’ and ‘end’ date of the month you are monitoring.

When you have selected the correct dates, click CONFIRM. This will change the graph and show you the data for the selected month. From here, click the REPORT icon from the top right hand bar of the page. This will produce a comment box – here access **Tutela Monthly Monitoring & Maintenance Checklist** in Appendix B and work through the check points.

When all check points have been completed copy the text into the comments box on the reporting page and click CONFIRM. By clicking confirm you are taking responsibility for the work being carried out correctly.

After the text has been copied over, click CONFIRM, and then CONFIRM again to select saving the report ‘To electronic library’. This will then automatically save the report on the library tab of the chosen piece of equipment under ‘Reports Pending Secondary Sign Off’. From here the report can be viewed and ACCEPTED by another R&D Associate Practitioner with Admin Privileges. To accept a report as a secondary R&D Staff member, view the report thoroughly and select ACCEPT in the blue box (located on the top left of the screen).

4.8 Monitoring/Audit or Inspection visits form study sponsors or regulatory bodies.

In a scenario where a regulatory body or study sponsor would like access to monitor the performance of R&D Laboratory Equipment a request to do so can be made by contacting labresearch@york.nhs.uk

From here, an account can either be created for them to monitor equipment at their convenience or R&D Associate Practitioners can create custom reports on request for specific pieces of equipment between defined time and date intervals.

5.0 Related SOPs and Documents

- Laboratory QA Checklist
- **R&D/S94 - Processing Laboratory Research Samples**

6.0 Appendix A

Out of Hours Procedure –

Log onto Tutela and click on the flashing RED Sensor alarm across from York – R&D. This will then take you to a screen listing equipment. From here you can see information about the incident. You should pay close attention to viewing the 'graph' section on the alarmed piece of equipment to see the current and previous trend of the temperature.

Details of icons referenced throughout this Appendix can be found in **4.2 Overview of the system.**

- **If Biochemistry Equipment is alarming**, make an assessment on the temperature change over a 10 minute period via Tutela, if the temperature appears to be going towards the normal range then do not make immediate arrangements to travel to York Teaching Hospitals NHS Foundation Trust.
- If the temperature does not appear to be coming back into the acceptable range within this time period call the biochemistry on 01904 725802 for LABORATORY MEDICINE/BIOCHEMISTRY EQUIPMENT ONLY. The Shift Biomedical Scientist will be on duty – ask them to inspect the piece of equipment and report back on a possible cause.

If the cause is obvious – you should allow them to rectify the issue and then yourself complete the incident report by referring to section **4.3 Managing Incidents**. This report should then be countersigned by another member of R&D Laboratory Staff.

If the cause is not obvious you should make arrangements to travel to York Teaching Hospitals NHS Foundation Trust to move the samples to their assigned back up locations as per the below table.

When moving freezer contents from Biochemistry to R&D – please inform the Shift Biomedical Scientist on 01904 725802.

- **If R&D Equipment is alarming** and does not appear to be coming back into the acceptable range after a 10 minute monitoring period you should make arrangement to travel to York Teaching Hospitals NHS Foundation Trust. Out of hours parking is available directly in front on the hospital in the disabled bays which are approved for staff between the hours of 6pm & 8am. The keys for each piece of R&D equipment can be located in the designated drawer.

On arrival work through the below points:

- Checking the door to the fridge/freezer has not been left open.
- Check the door has complete interaction with the seal.
- Aim to identify the cause of the derangement.

If the cause is clear (switched off, door open etc) and can be rectified, do so and monitor the system until the temperature returns to the acceptable range.

If the cause is unclear, take action and begin planning to move the samples within the fridge/freezer to the back- up module assigned as per the below table. Within the R&D and the Protein Lab (S2 9) there will always be a

Styrofoam transport box above a freezer labelled 'R&D Laboratory Service – Out of Hours Sample Transport'. This box should be used to transport the samples.

Remove contents of the fridge/freezer using blue protective climate gloves to an alternative location as noted in the below table to ensure the contents are kept at the required temperature.

After the incident has been resolved you should complete the incident report by referring to section **4.3 Managing Incidents**. This report should then be countersigned by another member of R&D Laboratory Staff.

<u>Equipment Alarming</u>	<u>Tutela Channel</u>	<u>Location</u>	<u>Move Contents To:</u>	<u>Location</u>
Alpha -80 Protein Lab	1017A	BIOCHEM – Rm. S2-9	Freezer Bravo (-80C)	R&D Lab (Right)
Charlie -20 Balance Room	1021A	BIOCHEM – Rm S2-4	Freezer Golf (-20C)	R&D (Centre Unit)
Freezer Bravo (-80C)	1022A	R&D Lab (Right)	Freezer Foxtrot (-80C)	R&D Lab (Left)
Freezer Foxtrot (-80C)	1023A	R&D Lab (Left)	Freezer Bravo (-80C)	R&D Lab (Right)
Freezer Golf (-20C)	1024A	R&D (Centre Unit)	Charlie -20 Balance Room	BIOCHEM – Rm S2-4
Fridge Golf	1024B	R&D (Centre Unit)	Fridge Oscar	BIOCHEM – Rm S2-9
Fridge Oscar	TBC	BIOCHEM – Rm S2-9	Fridge Golf	R&D (Centre Unit)

If at any time you feel unsure of the choice you are making – call one of the following for a second opinion.

01904 725887 R&D Office
07789 174492 R&D Mobile

If you need any technical assistance, Tutela can be contacted 24/7 on +44 1252 406 361 and quoting site: **NHSYTH0372**.

The next day you should discuss with the appropriate member of staff the action you took overnight and discuss preventative actions for the future alongside Tutela.

7.0 Appendix B

Tutela Monthly Monitoring & Maintenance Checklist

By creating a report for the above month I am acknowledging I have completed the following tasks;

1) Cleaning of Cabinet

- Cabinet should be cleaned on a monthly basis
- Use a Isopropanol 70% wipe to clear off dust/dirt from the outside of the cabinet

2) Clean Condenser Filter (Freezer Only)

- Should be cleaned monthly even if the check lamp is not on
- The filter is located on the front of freezer, lower right-hand side
- Open the grill by pulling the top of the grill towards you
- Take out the filter
- Wash the filter with water and then dry on absorbent paper
- Replace the filter and the grill
- Check the filter check lamp is off in the event the check lamp is on

3) Check Seals

- Check for cracks and signs of wear & tear.

4) Check Ice Build Up (Freezer Only)

- Is the volume of air in the space reduced? YES/NO
- Is defrost necessary in the next calendar month? YES/NO

Additional Comments: (insert any concerns or state N/A)