

R&D Laboratory Connected Automated Monitoring + Temperature Monitoring System

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

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: <https://www.research.yorkhospitals.nhs.uk/sops-and-guidance/> and/or Q-Pulse

SOP Reference:	R&D/S41
Version Number:	3.0
Author:	Laura Griffiths
Implementation date of current version:	16 th August 2023

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Date:	19 th July 2023
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	19 th July 2023

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	Reviewers	Details of significant changes
1.0	14 th September 2018		New document
2.0	15 th June 2020		Change of link to R&D website. Local changes & updates
3.0	16 th August 2023	Laura Griffiths	Change of author.

Contents

	<u>Page No</u>
1 Introduction, Background and Purpose	1
2 Who Should Use This SOP	2
3 When this SOP Should be Used	2
4 Procedure(s)	3
5 Related SOPs and Documents	11
6 Appendix A	8
7 Appendix B	10

1.0 Introduction, Background and Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the correct use of 'Connected Automated Monitoring + (checkit.net)' – 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, associated study documentation or written confirmation from the study sponsor). Records detailing the storage location and duration of research samples for each individual study prior to shipping and/or analysis are maintained within the study Laboratory File, ensuring a full chain of custody of research samples at York Trust sites.

Ongoing monitoring of ambient laboratories, refrigerators and freezers used to store research samples is conducted using 'checkit.net' monitoring systems, to identify and maintain a complete log of temperature records and any temperature excursions. The checkit.net 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 a complete record of temperature monitoring, including records of actions taken in the event of a temperature excursion (an online alarm incident facility). Combinations 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 five minute intervals and are 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 checkit.net 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 the resolution of the incident. checkit.net 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 checkit.net website, the action to be taken if an incident alarm is raised by checkit.net, how to manage isolations and how temperatures are monitored on the checkit.net system. The system is used to streamline temperature monitoring within Laboratory Medicine and R&D. The main improvements that checkit.net offers are:

- Automatically recorded temperature readings
- Consistent weekend and out-of-hours 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

This SOP should be used **when an incident occurs** for the following;

- For guidance in an alarmed situation for nominated staff during routine hours (see section 4.3)
- For guidance in an alarmed situation for nominated staff during out-of-hours (see Appendix A)

This SOP should be used **daily** for the following;

- General day to day performance monitoring of R&D fridges & freezers, and for checking the readings (see section 4.2)

This SOP should be used **monthly** for the following;

- Recording and reviewing incidents for patterns, and where necessary escalating to R&D (see section 4.7 'Reports')
- Completing and recording monthly maintenance (see section 4.6 'Monthly Monitoring of Temperature Records and Incidents')

This SOP should be used **quarterly/annually** for the following;

- When making monthly maintenance and incident records available for review at the R&D quarterly QA meetings and also to identify emerging patterns (see section Quality Assurance; Quarterly and Annual Review)

4.0 Procedure(s)

4.1 Overview of the system

checkit.net System is installed for Temperature Control across both sites & Scarborough.

The checkit.net website is accessed using the following link:

[Connected Automated Monitoring \(checkit.net\)](#)

Connected Automated Monitoring +
Formerly known as Tutela

HOW TO CONTACT US

EUROPE
SUPPORT
P: +44 1252 406 361
E: tutelausupport@checkit.net

SERVICE
P: +44 1252 406 345
E: tutelaservices@checkit.net
www.checkit.net

NORTH AMERICA
SUPPORT
P: +1 941 462 1067
E: tutelausupport@checkit.net

SERVICE
P: +1 941 462 1067
E: tutelasupport@checkit.net
www.tutelausa.com

SERVICE STATUS
Connected Automated Monitoring (CAM+) V4.3.3.7 has been released on the 29th June 2023. The release notes can be viewed in the websites document library under the user manual directory.

checkit.net London Company number 2061711
checkit.net London Company number 2061711
Copyright © Connected Automated Monitoring (CAM) 2023 Version: 3.3.7
Privacy Policy | Terms

- To log into the system enter user name (work email address) and password
- On the first occasion of logging into the system, terms and conditions (displayed on screen) will need to be accepted
 - The generic password will need to be reset in the webpages that follow
 - The PIN code which acts as an electronic signature when dealing with incidents will also need to be reset. To reset the PIN code;
 - Select 'Reset Pin Code' from the log in screen
 - Enter username (email address) and email address
 - A randomly generated 9-digit PIN will be sent via email

Once logged in, the home screen will be displayed.

The main home screen displays a list of locations that contain temperature-monitored equipment within the Trust.

The following icons are also displayed;



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.



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

By clicking on the sensors icon, it will display a list of sensors in that room (as shown below), with a current value for each, the option to view temperature records in graphs or tables and the option to manage incidents and isolations.

Connected Automated Monitoring +
Formerly known as Tutela

User: Laura.Griffiths@york.nhs.uk

SENSOR LIST - NHSYTH0372 - York - R&D

CHANNEL	DESCRIPTION	VALUES	GRAPHS	TABLE	INCIDENT	ISOLATIONS	BATTERY
1017A	ALPHA -80°C (Protein Lab)	-83.3 °C	⏪	⏩	🚨	🟢	🔋
1021A	CHARLIE -20°C (Balance Room)	-17.7 °C	⏪	⏩	🚨	🟢	🔋
1022A	BRAVO -80°C (Larc)	-80.4 °C	⏪	⏩	🚨	🟢	🔋
1023A	FOXTROT -80°C (Larc)	-81.7 °C	⏪	⏩	🚨	🟢	🔋
1024A	GOLF -20°C (Larc)	-19.8 °C	⏪	⏩	🚨	🟢	🔋
1024B	GOLF 2-8°C (Larc)	4.9 °C	⏪	⏩	🚨	🟢	🔋
1027A	OSCAR 2-8°C (Protein Lab)	3.8 °C	⏪	⏩	🚨	🟢	🔋
1020A	KILO Ambient (Protein Lab)	22.2 °C	⏪	⏩	🚨	🟢	🔋
1025A	JULIET Ambient (Larc)	20.3 °C	⏪	⏩	🚨	🟢	🔋

View Sensors
View Incidents
Check Readings
Manage Isolations
Compare Graphs
View Settings
Dashboard Displays

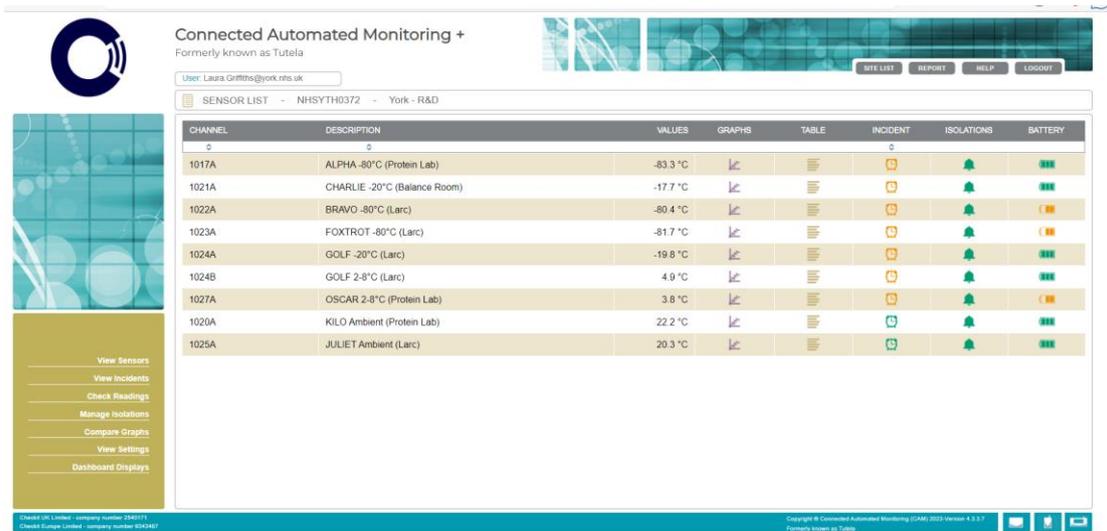
Copyright © Connected Automated Monitoring (CAM) 2023 Version: 4.3.5.7
Formerly known as Tutela

- The most recent recorded value will be displayed alongside each sensor
- By selecting the graph icon, a graph of the temperature throughout the day will be displayed
 - The data from previous days can be viewed by using the arrows on the left-hand side menu
- By selecting the table icon, a table will be displayed containing all recorded values taken that day (including minimum and maximum temperatures, as well as an average for the day)
 - More data can be viewed by using the arrows on the left hand side menu
- The Incident icon will display a list of any incidents on the sensor
- The Isolations icon will allow you to view the isolation status of a sensor (if you have permission you can manage isolations for this sensor)

4.2 Performing Daily Temperature Checks

To ensure the checkit.net monitoring system is performing correctly a 'Check Readings' should be performed daily for both 'York - R&D' and 'Scarborough Porto Cabin Store'. **It is important that this is performed on each working day by the team member who is working on site.**

By clicking on the sensor icon for a specific location (e.g. York – R&D) from the home page, the most recent recorded temperature value will be displayed for each sensor within the location, as shown below.



To 'Check Readings', click on the *Check Readings* tab on the left-hand menu displayed in the location-specific sensor list (the tab can be seen on the above image). By performing a 'Check Readings', a real-time temperature value will be shown for each item every time the page is refreshed, alongside the set point and delay settings for a low and high alarm.



Additionally, when any research samples are stored at Scarborough Labs, 'view incidents' for Scarborough sensors should be performed on a 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 are taken as required. To assess, 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 of the predefined temperature range

If an incident alarm is generated by checkit.net corrective action should be taken (detailed below). If this occurs during routine working hours, R&D Associate Practitioners are expected to accept and clear the incident via Tutela

- 4.3.1 Log into checkit.net and click on the flashing RED sensor alarm (sensors monitored by R&D staff will either be in the 'York – R&D' or 'Scarborough Porto Cabin Store' rows)
- 4.3.2 A list of equipment will be shown; the piece of equipment alarming will have a flashing red alarm in the '*incident*' column – click on this alarm
- 4.3.3 A screen will show information detailing the active incident alongside recent previously closed incidents
- 4.3.4 Click on the graph tab in the row of the active incident, to observe the current and previous trend of the temperature
- 4.3.5 Once the nature of the incident has been identified (low temp. or high temp. alarm), actions should be taken to bring the temperature back into range. This can include some or all of the following:
 - Check the door to a piece of equipment has not been left open
 - Remove ice from the seals of fridges and freezers to ensure the doors can close properly
 - Ensure that nothing is touching the temperature probe and potentially skewing readings (e.g. ice packs that have been at room temp. returned to the freezer and placed near a probe)
 - If the incident is a result of the door being open for long periods of time, ask staff members if they can keep it closed until the temperature of the apparatus comes back into range
 - Adjust the thermostat control
 - Close any windows (in the event of a low temp. alarm for an ambient room)
 - Adjusting (if necessary) the air conditioning to control room temperature, after discussing the change with a section senior in Biochemistry (specific to Kilo)
- 4.3.6 Once corrective action has been taken the apparatus should be monitored until it comes into and remains in range
- 4.3.7 The incident audit then needs to be completed by the appropriate member of staff (R&D healthcare science associate practitioner [HSAP] who received the call or took responsibility from a BMS or R&D team member), the supervisory sign off then needs to be completed by a different member of the HSAP team (see section 4.4).

If the suggestions detailed above (4.3.5) are not applicable or do not work, the following things may need to be considered;

- The freezer may need to be defrosted to ensure that it is working efficiently
- Facilities may need to be contacted to request an engineer
- Contents of fridges/freezers may need to be moved to an alternative location to ensure the contents are kept at the required temperature (see **Appendix A** for alternative storage)

Devices ultimately may need to be condemned and replaced if necessary.

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:

- *Cause Identified;* Identify the cause of the problem
- *Corrective Action Taken;* Take appropriate action to resolve the problem
- *Incident Resolved;* Validate that the problem has been resolved
- *Supervisory Sign Off;* Verify the incident has been resolved & sign off

For York Site: checkit.net 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 the 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 equipment containing research samples at Scarborough, daily as part of The Laboratory QA Checklist.

Equipment that store trial samples at SGH are as follows:

- Main Porto Cabin Store – Channel 2013A

To action an exception alarm:

4.4.1 Log into checkit.net

- 4.4.2 Identify the alarm on the system (it will be flashing red within the sensor column)
- 4.4.3 Click on the flashing alarm (sensors monitored by R&D are within 'York – R&D' and 'Scarborough-Porto Cabin Store')
- 4.4.4 The sensor list for the specific location will be shown, click on the flashing alarm within the incident column (this will still be red)
- 4.4.5 Information on the active alarm will be displayed alongside previous recent incidents, click on the new active alarm (flashing red) within the audit column
- 4.4.6 The incident Audit screen will now be displayed, which is made up of three boxes containing information regarding the incident (shown and summarized below)

1. Incident summary. Information includes the type of alarm, the date/time of alarm and a summary of the occurrence. Each incident is also assigned an Incident Audit ID.
2. Alarm Call Audit Trail. This box contains the order of operations followed by checkit.net once an alarm has been triggered
3. Incident Audit Report. Each line needs to be completed to clear the alarm. Once 'cause identified' is populated, the audit icon will change from red to orange. After all sections have been populated and the 'Supervisory Sign Off' completed, the alarm will change from orange to green.

4.4.7 The Incident Audit Report (section 3 per the above image) must now be

The screenshot displays the 'Connected Automated Monitoring +' interface. It features a navigation menu on the left with options like 'View Sensors', 'View Incidents', and 'Check Readings'. The main content area is titled 'INCIDENT AUDIT - NHSYTH0372 - York & Scarborough Pathology'. It is divided into three sections:

- Section 1 (Incident Summary):** Shows 'Alarm type: High Temperature Alarm', 'Alarm received: 13/07/2023 12:25:25', and 'Alarm called out by: ACH User'. It also displays '1017A HIGH TEMPERATURE ALARM CURRENT VALUE: 52.21C'.
- Section 2 (Alarm Call Audit Trail):** A table with columns for time, action, and user. The actions include 'Alarm Received', 'Call Lab Research Office (No Answer)', 'Call Lab Research Mobile (Answering Machine Left Message)', 'Call Laura Griffiths (Alarm Accepted)', 'Email Laura.Griffiths@york.nhs.uk', and 'Incident Closed'.
- Section 3 (Incident Audit Report):** A table with columns for 'By', 'Date/Time', and 'Edit Report'. It contains entries for 'Cause Identified' (by jae.lee@nhs.net at 17/07/2023 12:39), 'Controlling Task' (by jae.lee@nhs.net at 17/07/2023 12:40), and 'Incident Resolved' (by jae.lee@nhs.net at 17/07/2023 12:41). There is also a 'Supervisory Sign Off' field.

completed by the appropriate member of staff (staff member who received the call)

- 4.4.7.1 Identify the cause of the incident and enter into the 'Cause Identified' box. This could be a result of a number of things (including and not limited to);
 - Stock check
 - Reagent delivery storage
 - Door left open
 - Ice covering the seal impeding proper closure
 - Items placed over the probes, leading to skewed results

- Window open
- Air conditioning turned off/down

4.4.7.2 Once the cause has been identified, steps can be taken to resolve the issue and bring the apparatus temperature back within range (as described in Section 4.3). Action taken should be entered within the 'Corrective Action Taken' box, ensuring the following is detailed;

- The extent and duration of the temperature excursion
- Whether research samples were present
- If present, an assessment of the impact on sample(s) integrity

4.4.7.3 Once the incident has been resolved complete the 'Incident Resolved' box, summarizing the cause and extent of the temperature deviation, the corrective actions taken and any preventative actions required

4.4.7.4 The 'Supervisory Sign Off' box will then be completed by a different member of the HSAP team to sign off and complete the incident. Incidents should only be signed off when they have been fully resolved and the following has been done;

- The cause(s) has been identified
- The impact assessment has been completed
- All CAPAs completed
- The unit or room is maintaining its temperature
- The data is being uploaded to the cloud

A full report of the incident can be viewed by selecting the 'View report' icon found under the Incident Audit Report Box (highlighted in the above image).

A list of all incidents, open, pending and closed for each location can be found by clicking the 'View Incidents link' on the left-hand side of the sensor list screen (the page brought up once a location has been selected from the home screen), this will bring you to the Site Incident History.

Connected Automated Monitoring +
Formerly known as Tutela

User: Laura.Griffiths@york.nhs.uk

SITE INCIDENT HISTORY - NHSYTH0372 - York & Scarborough Pathology

ALARM ID	ALARM TYPE	SENSOR REF	DESCRIPTION	RECV TIME	CALL TIME	AUDIT	GRAPH
35904378	High Temperature Alarm	1024A	GOLF -20°C (Larc)	14/07/2023 09:41:22	14/07/2023 09:42:23		
35903817	High Temperature Alarm	1021A	CHARLIE -20°C (Balance Room)	14/07/2023 08:38:05	14/07/2023 08:40:18		
35903636	High Temperature Alarm	1021A	CHARLIE -20°C (Balance Room)	14/07/2023 08:14:05	14/07/2023 08:17:16		
35902679	High Temperature Alarm	1021A	CHARLIE -20°C (Balance Room)	14/07/2023 06:49:04	14/07/2023 06:52:17		
35902366	High Temperature Alarm	1021A	CHARLIE -20°C (Balance Room)	14/07/2023 06:05:04	14/07/2023 06:08:13		
35896304	High Temperature Alarm	1021A	CHARLIE -20°C (Balance Room)	13/07/2023 16:19:05	13/07/2023 16:23:29		
35895175	High Temperature Alarm	1021A	CHARLIE -20°C (Balance Room)	13/07/2023 14:08:05	13/07/2023 14:11:18		
35894670	High Temperature Alarm	1024B	GOLF 2-8°C (Larc)	13/07/2023 13:08:24	13/07/2023 13:10:50		
35894667	High Temperature Alarm	1022A	BRAVO -80°C (Larc)	13/07/2023 13:08:08	13/07/2023 13:13:44		
35894618	High Temperature Alarm	1023A	FOXTROT -80°C (Larc)	13/07/2023 13:02:16	13/07/2023 13:06:29		
35894352	High Temperature Alarm	1021A	CHARLIE -20°C (Balance Room)	13/07/2023 12:28:06	13/07/2023 12:31:16		
35894334	High Temperature Alarm	1017A	ALPHA -80°C (Protein Lab)	13/07/2023 12:28:25	13/07/2023 12:29:38		
35800395	Low Temperature Alarm	1027A	OSCAR 2-8°C (Protein Lab)	10/07/2023 16:39:09	10/07/2023 16:42:36		
35746940	Transmitter Off-line Cleared	1017A	ALPHA -80°C (Protein Lab)	30/06/2023 10:38:41	30/06/2023 10:39:56		
35746936	Transmitter Off-line	1017A	ALPHA -80°C (Protein Lab)	30/06/2023 10:38:01	30/06/2023 10:38:58		
35746816	Transmitter Off-line Cleared	1017A	ALPHA -80°C (Protein Lab)	30/06/2023 10:22:41	30/06/2023 10:26:05		

4.5 Managing Isolations

Please make sure to put sensors in isolation (inactivating the alarm) when required to avoid unnecessary phone calls from checkit.net, for when defrosting a freezer only.

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 a monthly basis.

Incident Reports 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 checkit.net 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;

- 4.7.1 Log in and access the home page
- 4.7.2 Retrieve the list of sensors in a certain location by clicking on the sensor icon in the appropriate row (R&D team members will only report on sensors in 'York – R&D' or 'Scarborough Porto Cabin Store')
- 4.7.3 Select the piece of equipment to be reported on by selecting the graph icon in the appropriate row
- 4.7.4 Click on the 'Calendar' tab (top left blue box), and select the 'start' and 'end' date of the time period to be monitored
- 4.7.5 Once the correct dates have been selected, click 'Confirm'

- 4.7.6 The graph will update to display the data for the specified time period, the report can now be generated by selecting the 'Report' tab (top right hand bar, along from 'log out')
- 4.7.7 A comment box will be displayed, allowing information to be documented alongside the report;
- If the report is for monthly monitoring access 'checkit.net Monthly Monitoring & Maintenance Checklist' in Appendix B, and work through the check points, once completed, copy the text into the comment box
 - If reports are being gathered for any other purpose (e.g. to summarise a deviation relating to a temperature excursion, or to monitor certain temperature patterns) document appropriate information, including the purpose of the report and what it shows within the comment box
- 4.7.8 Once all information has been entered into the comment box (displayed at step 4.7.7) on the reporting page, click 'Confirm' (by clicking 'Confirm' the user is taking responsibility for the work being carried out)
- 4.7.9 Select '*printer*' as the required output and click 'Confirm'
- 4.7.10 The report will be opened in a separate internet tab, the report can now be saved in the appropriate 'EQUIPMENT' folder on the electronic drive [Laboratory M > Biochemistry > 0.1 Trials Info > EQUIPMENT]

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 the R&D lab team - yhs-tr.labresearch@nhs.net

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.

5.05.0 Related SOPs and Documents

- **Laboratory QA Checklist**

R&D/S94 - Processing Laboratory Research Samples

6.0 Appendix A

Procedure upon receipt of an out-of-hours alarm;

- Log into checkit.net and click on the flashing RED sensor alarm (responsible for those in the 'York – R&D' row only)
- A list of equipment will be shown; the piece of equipment alarming will have a flashing red alarm in the 'incident' column – click on this alarm
- A screen will show information detailing the active incident alongside recent previously closed incidents
- Click on the graph tab in the row of the active incident, this is **important** to observe the current and previous trend of the temperature

Details of icons referenced and present on screen can be found in Section 4.1 Overview of the System

- **If Equipment is alarming within Biochemistry**, make an assessment on the temperature change over a 10-minute period via checkit.net, 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 department 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 – the BMS should rectify the situation, while the R&D staff member who received the alarm should complete the incident report by referring to section **4.4 Managing Incidents**. This report should then be countersigned by another member of R&D Laboratory Staff.

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

If freezer contents are to be moved from Biochemistry to R&D, please inform the Shift Biomedical Scientist on 01904 725802.

- **If Equipment is alarming within the LaRC Laboratory** and does not appear to be coming back into the acceptable range after a 10-minute monitoring period, arrangements should be made to travel to York and Scarborough 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:

- Check the door of 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 (further information can be found in **section 4.3**) and begin planning to move the samples within the fridge/freezer to the back- up module assigned as per the table below. Within both labs (LaRC & biochemistry [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 table below to ensure the contents are kept at the required temperature.

After the incident has been resolved, the incident report should be completed by referring to **section 4.4 Managing Incidents**. This report should then be countersigned by another member of R&D Laboratory Staff.

<u>Equipment Alarming</u>	<u>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)

Call one of the following people for a second opinion if uncertain at any point.

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

If technical assistance is needed, checkit.net can be contacted 24/7 on +44 1252 406 361 and quoting site: **NHSYTH0372**.

Action taken overnight and discussions around preventative actions for the future should be discussed with the appropriate members of staff (R&D Lab Team).

7.0 Appendix B

checkit.net **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)