

Glasgow Clinical Trials Unit Guideline

Guideline number	17.006C	Version	2.0
Title	GCRF Checkit Fridge/Freezer Management System		

MANDATORY

Immediate actions in the event of an alarm received by Nurse Coordinator/Research Nurse Manager:

During CRF working hours Monday-Friday 0800-1700 hrs Checkit alerts will be actioned by CRF Research Nurse and Nurse Coordinator. Out of hours including weekends the alerts will be actioned by CRF Research Nurse Manager.

- Check Checkit system to view temperature excursion.
- Check fridge/freezer interior manually – do not rely on door temperature.
- If evidence of defrosting look at immediate options for removal of samples and seek further advice from Nurse Manager.
- If no evidence of defrosting or warming move probe to ensure correct circulation around sensor.

Appliances using Checkit are only present in the following locations

- QEUH ICU research office on level 1 of the main building - requires swipe card access plus a key (held in GCRF).

Actions for Nurse Coordinator

1. Review Checkit online system. Login details can be found on GCRF common drive CRF sites folder.

a) Dashboard should look as below:

Connected Automated Monitoring +
Formerly known as Tutela

User:

SITES & DEPARTMENTS -

Site ID	Site Name	Audit Users	Contacts	Sensors	Library
NHSGCRFICU	Queen Elizabeth University Hospital CRF ICU				
	CRF ICU (WARP)				
NHSGCRFL4	Queen Elizabeth University Hospital CRF Level 4				
	CRF Level 4				
NHSGGC	Asthma Research Group				
	GGC Bio-repository - Asthma Research Group				
	GGC Bio-repository - Asthma Research Group (WARP)				

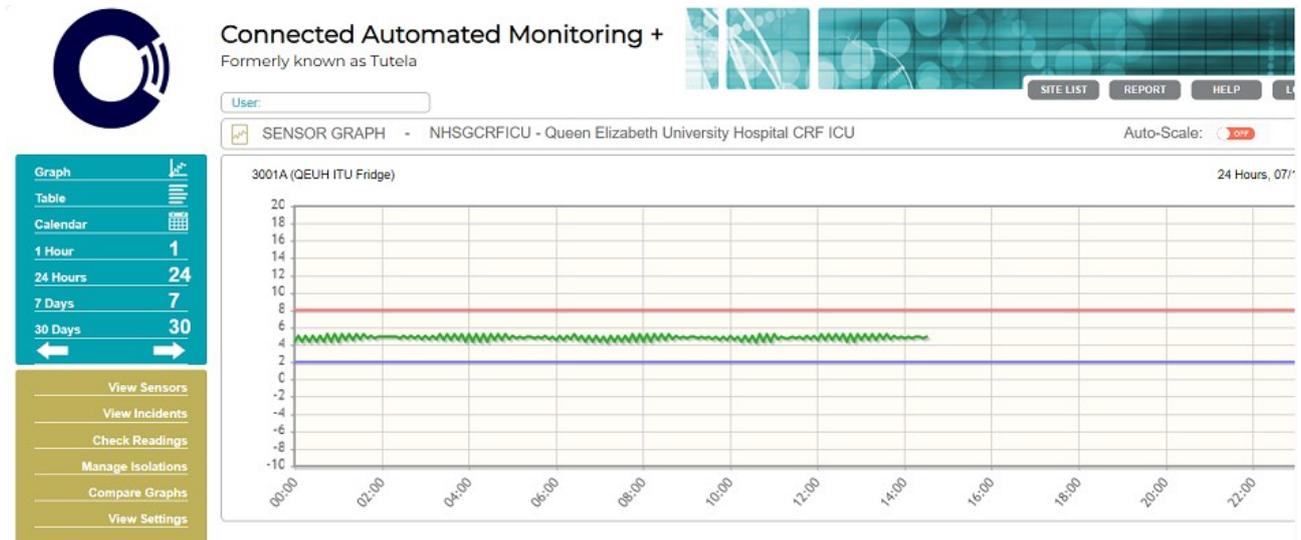
Left sidebar menu: Floorplan Displays, Edit Profile, Training

Top right navigation: SITE LIST, REPORT, HELP

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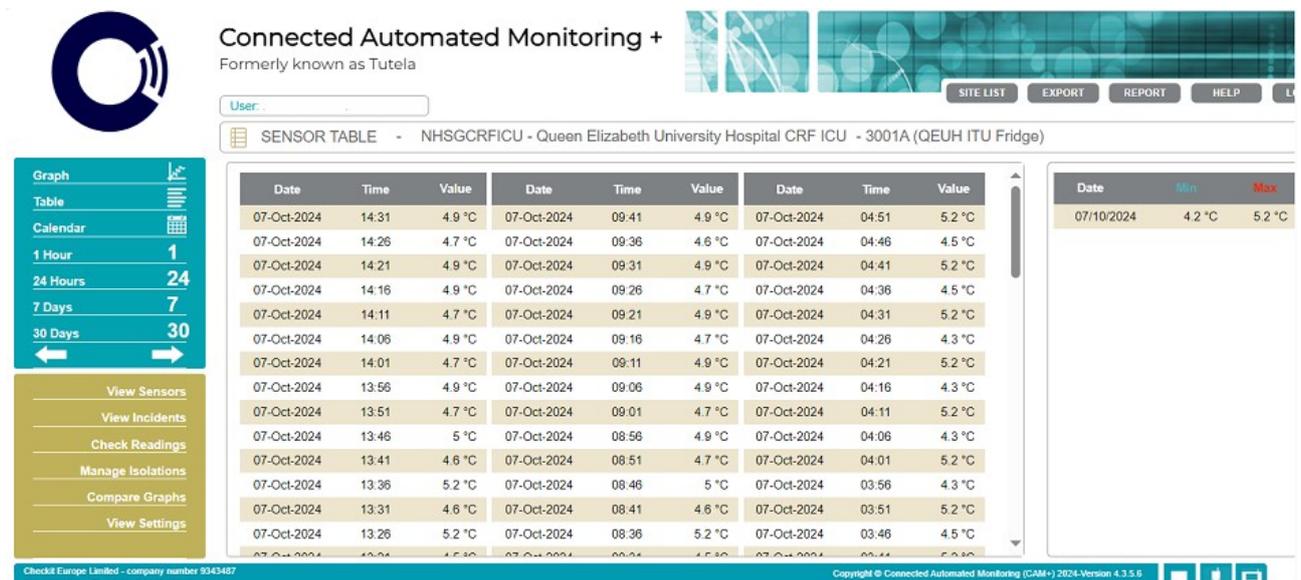
NB: Red highlight indicates an active alarm.

b) Select the Sensor from the list, Select appropriate Graph. Graph is displayed below.



c) Review green trace. Look for spikes in the temperature graph which might indicate freezer/fridge door being recently opened. This should not require action but must be observed. If a general trend upwards is seen, this may indicate an issue with either the freezer/fridge or the probe.

d) The trace from the previous 7/30 days can also be displayed using Sensor list, Click on table



e) Nurse coordinator should manually review appliance once made aware of alert. If clear evidence of defrosting/ warming is present (i.e. not hard frost in -80 or watery residue in the -40 freezer) move on to section h. If there is no evidence of defrosting/warming, then observe on Checkit for a further 30 mins.

f) If after 30 mins, the temperature is returning to range, then continue observation until back within range. Checkit Probe updates the system every 5 minutes, so it may require 1 hour of observation to see the trend. Move on to section i to enter Corrective Action once the appliance is stable.

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- g) If temperature not returning to within range after 30 mins, then escalate to Nurse Manager and move to section h.
- h) If clear evidence of defrosting/warming OR temperature not returning to range after observation:
- Consider movement of samples to another freezer/fridge.
 - Ensure all logs are reviewed for samples present and contact investigators to see if samples can be stored at an alternative temperature (i.e. samples from -40 freezer being stored in the -80). If they cannot be contacted, or it is time critical, then samples should be moved even without investigator approval.
 - Ensure all Lead Study Nurses are informed via email that they should make their sponsors aware of need for alternative storage.
 - Ensure all Lead Study Nurses are informed that they must update their freezer logs as soon as practicable. File note (Form 51.016M) must be created detailing dates of move, brief description of issues, resolution and location of temporary storage.
 - Complete corrective actions as per section i, with the action stating, **samples relocated**.
- i) To acknowledge a temperature excursion/alert, go into:

Site list select the sensor, select Incident, Click on the audit icon to the right-hand side

- j) Click on enter/ edit report pencil for each of the fields:

The screenshot displays the CAM+ interface for an incident audit. The header includes the logo, the text 'Connected Automated Monitoring + Formerly known as Tutela', and navigation buttons for 'SITE LIST', 'HELP', and 'LOG'. The main content area is titled 'INCIDENT AUDIT - NHSGGC - Asthma Research Group' and shows details for 'System 003 --20 Freezer'. The alarm incident ID is 40857293, with an alarm type of 'High Temp Alarm' and an alarm received time of 17/09/2024 12:29:12. The alarm was called out by 'ACH User'. The 'Alarm Call Audit Trail' table shows a sequence of events: Alarm Received, Call to Managers Phone, Email to @ggc.scot.nhs.uk, and Incident Closed. Below this, the 'Incident Audit Report' form has fields for 'Cause Identified', 'Corrective Action Taken', 'Incident Resolved', and 'Supervisory Sign Off', each with a 'View Report' icon.

Alarm Call Audit Trail			
1	17/09/2024 12:29:12		Alarm Received
2	17/09/2024 12:29:17	Call	Managers Phone (Answering Machine Left Message)
3	17/09/2024 12:30:16	Email	@ggc.scot.nhs.uk,
4	17/09/2024 12:30:15		Incident Closed

- k) Enter comment in each field as required
The corrective action requires to have a supervisory sign off this can be completed by any one of the nurse managers, Lead nurse or one of the Biomedical scientists at the bio-repository.
- l) You can check incident report has been acknowledged by clicking the view report icon. Screen should show text box as follows:

EXIT
REPORT

3001A - QEUH ITU Fridge

Alarm incident ID: 39081933 Alarm type: Transmitter Off-line

Alarm received: 25/05/2024 03:01:52 Alarm called out by: ACH User

Alarm Details: 3001A SENSOR TRANSMITTER FAILURE ALARM CURRENT VALUE: 4.5°C

Alarm Call Audit Trail

1	25/05/2024 03:01:52		Alarm Received
2	25/05/2024 03:01:55	Call	(ICUFDG)(OOH) Research Nurse Manager On call (Answering Machine Left Message)
3	25/05/2024 03:02:55	Call	(ICUFDG)(OOH) Research Nurse Manager On call (Answering Machine Left Message)
4	25/05/2024 03:03:55	Call	(ICUFDG)(OOH) Lead Nurse (Answering Machine Left Message)
5	25/05/2024 03:04:54	SMS	
6	25/05/2024 03:04:54	Email	
7	25/05/2024 03:04:53		Incident Closed

Incident Audit Report

INCIDENT CAUSE:

1.

11/06/2024 13:32

CORRECTIVE ACTION TAKEN:

1.

11/06/2024 13:32

INCIDENT CLEARED:

1.

11/06/2024 13:32

SUPERVISORY SIGN OFF:

1.

Guideline signatories

Prepared by Signature	Barbara McLaren	Date
Approved by Signature	Lynn Prentice	Date

Document history

Version	Date	Description
1.0	10.06.17	Creation of Guidance document
1.1	21.11.18	Minor update
2.0		Update to guidance template v2.0 Change to author Change of references from Tutela to Checkit and updated screenshots Addition of file note requirement

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