

Glasgow Clinical Trials Unit Guideline

Guideline number	17.006B	Version	2.0
Title	GCRF Kelsius Fridge/Freezer Management System		

MANDATORY

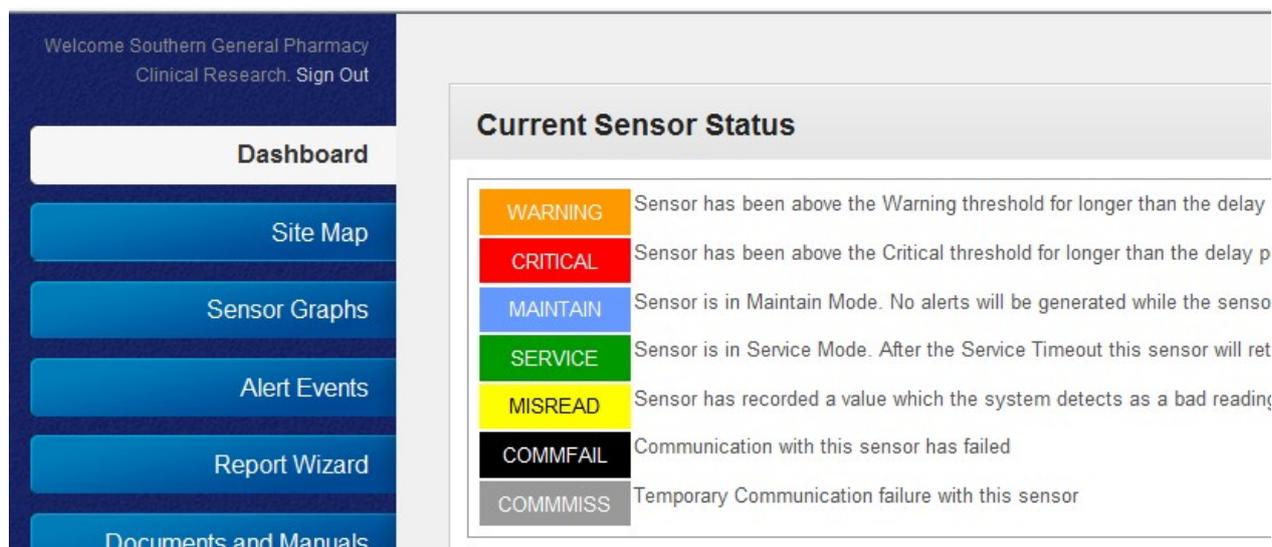
During CRF working hours Monday-Friday 0800-1700 hrs Kelsius alerts will be actioned by CRF Research Nurse and Nurse Coordinator. Out of hours including weekends the alerts will be actioned by CRF Research Nurse Manager.

1. During working hours the immediate actions in the event of an alarm on the Kelsius network controller box, or report received from admin team/email system:
 - Check Kelsius network controller box to view temperature excursion.
 - Log into the controller box with individual pin and place system into ACKALARM (this has replaced service) service mode (this will turn off alarm for 60 mins only). Instructions are on the wall beside Kelsius network controller box in Adult Nurse Base (QEUH) and on the wall in the main hot desk office (GRI) and within the lab of the CRF (GGH).
 - Check fridge/freezer interior manually – do not rely on door temperature.
 - If evidence of defrosting investigate immediate options for removal of samples and seek further advice from Research Nurse Manager.
 - If no evidence of defrosting or warming move probe to ensure correct circulation around sensor. Complete corrective actions as per section h and inform Nurse Coordinator

2. Actions for Nurse Coordinator/Research Nurse Manager

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

- a) Dashboard should look as below:



Welcome Southern General Pharmacy
Clinical Research. Sign Out

Dashboard

- Site Map
- Sensor Graphs
- Alert Events
- Report Wizard
- Documents and Manuals

Current Sensor Status

WARNING	Sensor has been above the Warning threshold for longer than the delay
CRITICAL	Sensor has been above the Critical threshold for longer than the delay p
MAINTAIN	Sensor is in Maintain Mode. No alerts will be generated while the senso
SERVICE	Sensor is in Service Mode. After the Service Timeout this sensor will ret
MISREAD	Sensor has recorded a value which the system detects as a bad reading
COMMFAIL	Communication with this sensor has failed
COMMISS	Temporary Communication failure with this sensor

- b) Click on **Sensor graphs, Temperature sensors**. Alter dropdown box as needed to view relevant appliance.

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Welcome Southern General Pharmacy
Clinical Research. Sign Out

Dashboard

Site Map

Sensor Graphs

Temperature Sensors

Temperature Sensor Groups

Historical Sensors

Alert Events

Report Wizard

Documents and Manuals

Configuration

Temperature Sensor Search

Quick Date Range: [v] Today [v]

Select a sensor from the list: Southern General Pharmacy Clinical Research ->

Download detailed records: [PDF] [Excel] [CSV]

■ -40 Freezer

CRITICAL -30.0

-29

-31

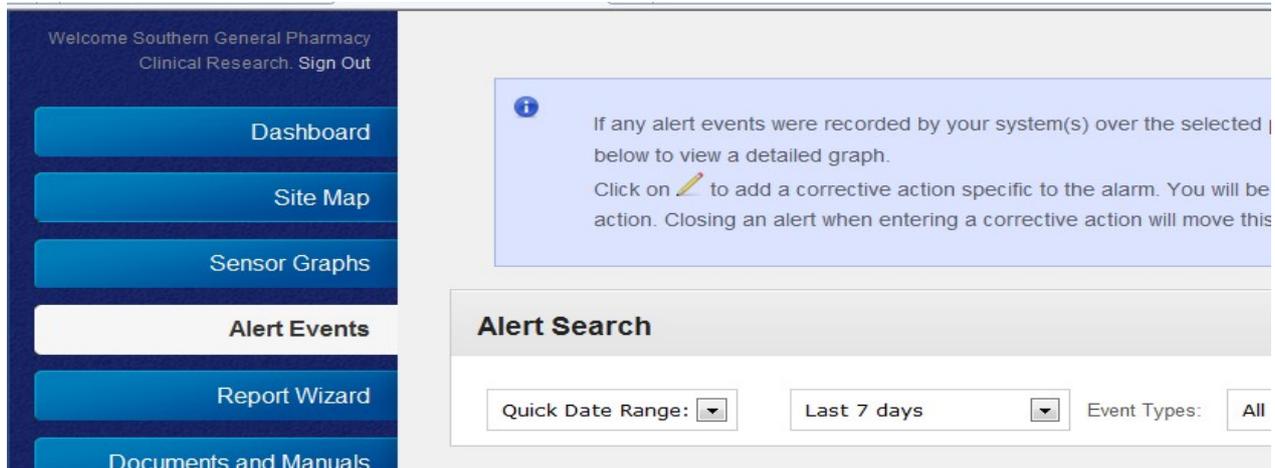
-32

-33

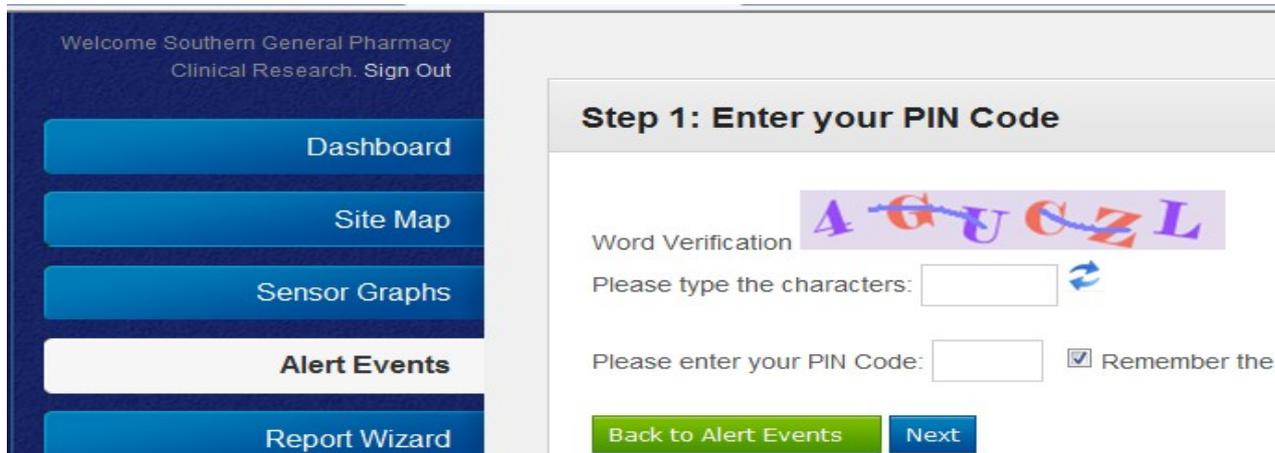
- c) Review trend. Look for spikes in the temperature graph which might indicate freezer door being recently opened. This should not require action but must be observed. If a general trend upwards is seen, this may indicate an issue with either the freezer or the probe.
- d) Nurse Coordinator/Research Nurse Manager 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 g. If there is no evidence of defrosting/warming, then observe on Kelsius for a further 30 minutes.
- e) If after 30 mins, the temperature is returning to range, then continue observation until back within range. Probe updates Kelsius system every 20 mins, so it may require 1 hour of observation to see the trend. Move on to section h to enter Corrective Action once the appliance is stable.
- f) If temperature not returning to within range after 30 mins, then escalate to Nurse Manager and move onto section g.
- g) If clear evidence of defrosting/warming OR temperature not returning to range after observation:
 - Consider movement of samples to another freezer or department
 - Ensure all freezer logs are reviewed for samples present and contact investigators (during working hours) 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 sample 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.

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- Complete corrective actions, with the action stating, **samples relocated**.
- h) Enter corrective action by accessing **Alert events**, which should list any outstanding alerts on the system. The system now has an option to close all alerts with one corrective action use as appropriate (see below):
- i) Click on pencil to right hand side of screen this is where the option to close all alerts will appear.

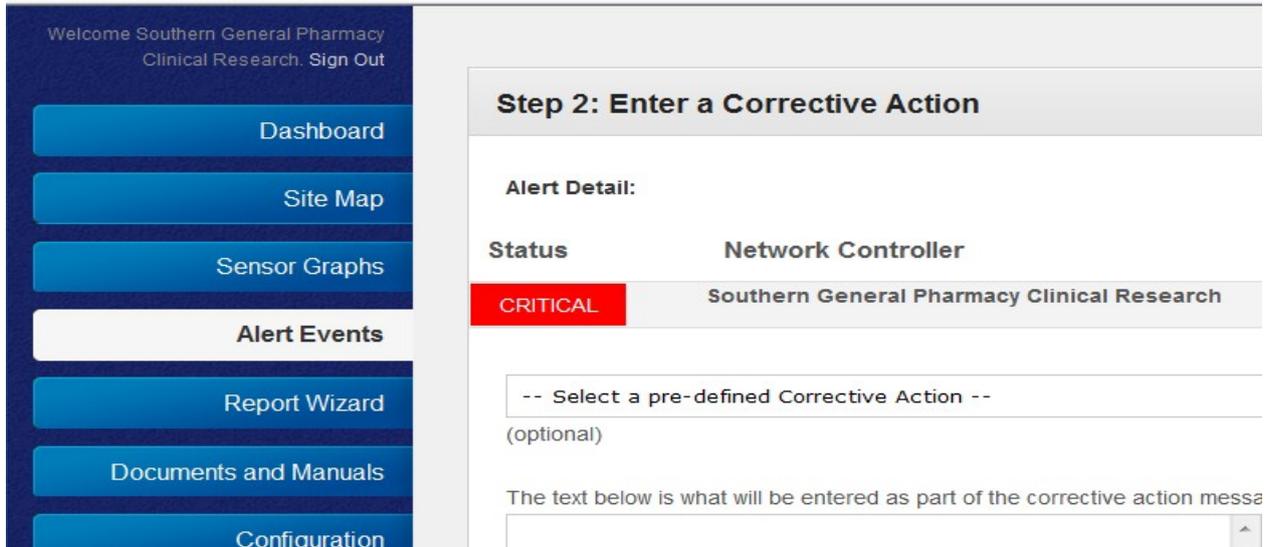


- j) Enter PIN code, remembering to untick the box for 'remember the code', or it will store your PIN for all future corrective actions.



- k) Click the dropdown to select a corrective action: NB: You can add free text comments if there is no appropriate option in the drop-down list.

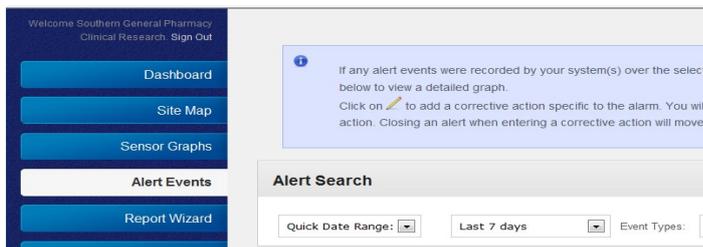
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l) **Remember** to tick the box to close the alert, or it will not resolve on the system



m) Save the action, screen will return to the main dashboard screen, with the following:



- n) If not appropriate to close all events with the same action then repeat for all outstanding corrective actions for this episode.
- o) If there are other outstanding actions

on the system, inform the Nurse Coordinator/Nurse Manager

Guideline signatories

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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 Minor admin changes Addition of file note creation Change to author

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