

Automated Medicines Temperature Monitoring Standing Operating Procedure

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1. Scope

- 1.1. South East Coast Ambulance (SECAmb) NHS Foundation Trust is committed to providing high quality patient care and the safe and secure management of medicines.
- 1.2. This procedure is applicable to all clinicians and also support staff engaged in the distribution and packing of drugs in the Trust and sets out the scope of practice to which they must adhere.
- 1.3. All medicines obtained for patient use within SECAmb are subject to appropriate assessment of their fitness for use. Appropriate storage and environmental conditions are specified for all medicines.
- 1.4. Exposure to high temperatures may accelerate the rate of degradation of medicines, reducing their effectiveness and shortening their shelf-life. If these medicines are then used to treat patients, it poses a potential risk to the health and wellbeing of the person receiving the medicine.
- 1.5. Medicines should be stored under conditions that ensure their quality is maintained. The temperature of storage is one of the most important factors that can affect the stability of a medicine.
- 1.6. Medicines not stored correctly may have a financial implication to the Trust through increased wastage and, if unavailable, may have a detrimental effect on the delivery of patient care.
- 1.7. Temperature monitoring of all areas where medicines are stored should take place on a daily basis. This involves recording the actual temperature as well as the maximum and minimum temperature over the previous 24 hours.
- 1.8. The Trust uses an Automatic temperature Monitoring system provided by a company called <u>Monika</u>.
- 1.9. The purpose of this procedure is to detail actions required for any out-ofrange temperature alerts, and how to interact with the Monika software and record actions in a timely manner.
- 1.10. A Monika sensor is placed in every room or drug refrigerator where medicines are stored. This includes operational Ambulance Stations and Make Ready sites, as well as specialist areas such as the Logistic stores at Telford Place and Paddock Wood, and the main Medicines Distribution Centre (MDC) based at Paddock Wood.
- 1.11. Ambient sensors are either mains powered, or battery operated, and all fridge sensors are battery powered. Attention should be given to the battery level status. It may be necessary to replace the batteries annually





or more frequently if the indicator suggests replacement is required (note that it takes 30 minutes for the sensor to come back online).

1.12. The sensor collects temperature data in these areas and sends it back to the Monika cloud server every 10 minutes throughout a 24-hour period.

2. **Responding to Alerts Procedure**

- 2.1. If the refrigerator temperature exceeds the required range (between 2°C to 8°C) for longer than 20 minutes, or the room temperature is outside of 15°C to 25°C for longer than 60 minutes, a "level 1" email alert will be sent to the relevant Operational Unit (OU) Leadership team or Logistics team and the Medicines Governance Team (MGT).
- 2.2. A level 1 email alert is also raised if a sensor has not taken a reading for over 30 minutes. The email will give brief details of the alert and its location.
- 2.3. Any identified fault reported should be investigated immediately and appropriate remedial action taken to resolve the fault.
- 2.4. A member of the OU leadership on duty will log into the Monika web client interface and select the appropriate site by clicking on the areas below the site name. Teams that only have one station assigned to their log-in can skip this step(see Appendix A).
- 2.5. Once the site is selected, the 'Live View' tab can be selected under the 'Apps' section of the dashboard. This will show the temperature status of each location being monitored by the Monika system. The colour of the box will change depending on the status (see Appendix B):
 - 1. A green box indicates the item is safely operating within its temperature settings.
 - 2. A red box indicates the temperature is too warm.
 - 3. A blue box indicates the temperature is too cold.
 - 4. Other information displayed includes the area, sensor name, live temperature, and battery status.
- 2.6. Full details of the alert can be accessed by clicking on the 'Alerts' tab under the 'Apps' section of the dashboard. This includes information about where and when the alert started, and the highest temperature reached whilst out of range (Appendix C).





- 2.7. The member of Group/Team must acknowledge an alert by clicking on the "Acknowledge" button.
- 2.8. Once acknowledged, corrective actions can be made to rectify the alert. The member of staff must check after 30 minutes that the corrective actions have resolved the issue.
- 2.9. The corrective action must be entered by clicking on the "corrective action" button. Note that a corrective action cannot be applied before the alert has first been acknowledged and should only be done when the area has returned to the normal range (see Appendix D).
- 2.10. The most appropriate action should be selected from the drop-down list and then click on the "Apply Corrective Action" button.
- 2.11. If choosing to add an "additional blank action", notes must be added through free text detailing the action taken to correct the issue. This is done by navigating to "Daily Diary" under the "Apps" section of the dashboard, and clicking "add comment" under the relevant alert.
- 2.12. The OU member <u>must</u> then add their name to the free text section as the person signing off the alert.
- 2.13. The alert should be investigated promptly. If an alert has not been acknowledged for longer than 6 hours, Monika will generate another alert email (also known as a "Level 2 alert") which will be sent to Tactical, the Medicines Team and the Operational Support Desk (OSD).
- 2.14. If an alert has been acknowledged, no further alarms will be raised even if the area remains out of temperature range. It is the duty of the person acknowledging the alarm to recheck the sensor 30 minutes afterwards to ensure the excursion has been remedied.
- 2.15. If the alert is out of hours, OSD will follow the flow chart in Appendix G until someone responds to the alert. It is the responsibility of the duty manager contacted by the OSD to follow up and investigate the alert. This will be recorded on Marvel for audit and will be followed up by the Medicines Team within hours (Monday-Friday, 0800-1600).
- 2.16. The duty manager can log into the Monika web client interface and acknowledge the report on the dashboard, adding their name to the free text section as the person signing off the alert.
- 2.17. In all cases where an alert has not been acknowledged for a period exceeding 6 hours, a Datix (DIF1) incident form must be completed.





- 2.18 Specialist areas (i.e. the MDC and Telford Place) that store medicines are unmanned at night, weekends and Bank Holidays. The Medicines Team will closely monitor when extremes of weather are forecast and take further action when required. Any alert that breaches the 6 hours will be escalated to the Operational Unit Manager (OUM) in the Incident Command hub who will investigate further.
- 2.19 Medicine fridges that require decommissioning under instruction from the MGT for a period, will be removed from the Monika full client system. They will appear grey on the dashboard and will not create alarms. Whilst decommissioned, the batteries should be removed to protect the sensor unit from leakage and degradation.
- 2.20 It is the OUs responsibility to sign the actions off correctly and this will be monitored by MGT.

3. Escalation Procedure

- 3.1. In the event of a temperature excursion where corrective action(s) fail to maintain adequate temperature levels, a Datix (DIF1) must be submitted and the MGT contacted for advice on the stability and suitability of the medicines.
- 3.2. If ambient medicines are or have been exposed to excessive heat (>25°C) or cold (<15°C), they must not be used. Inform your station / senior manager immediately. The affected medicines must be quarantined and separated from the live stock. The station/senior manager must be informed immediately and a Datix (DIF1) submitted.
- 3.3. If refrigerated medicines are or have been exposed to excessive heat (>8°C) or frozen (<0°C), these must not be used. The affected medicines must be quarantined and separated from the live stock. The station/senior manager must be informed immediately and a Datix (DIF1) submitted.
- 3.4. Another refrigerator must be used for any replacement stock until the issue is rectified. Inform Logistics and Medicines immediately so that fresh stock can be supplied to the station and quarantined stocks returned to the MDC.
- 3.5. Where the cause of the excursion has been identified, this should be rectified immediately. Preventative measures to prevent the reoccurrence should be put in place as quickly as possible.
- 3.6. If there is urgent operational need to get advice on the affected medicines or the excursion occurs out of hours (OOH), the strategic medical oncall must be contacted immediately for advice.





- 3.7. The quarantined medicines should be kept in the temperature-controlled medicines room to maintain the correct temperature and security measures.
- 3.8. A DIF1 (Datix) incident form must be completed for any breach of temperature regardless of whether it involves a refrigerator or a medicines room. This should include:
 - the affected medicines (batch number and expiry date)
 - the quantity of affected medicines
 - the exact duration of the temperature excursion and the temperature reached.
 - any causes/contributing factors for the excursion (if known)
 - actions taken to resolve the issue (including escalations)
- 3.9. If the temperature excursion timeframe is outside of the information available via the medicine's Summary of Product Characteristics (SmPC), the MGT will contact the manufacturer directly for advice on the suitability of use in regard to the temperature excursion.
- 3.10. The Chief Pharmacist or senior member of the MGT should be consulted before disseminating or acting on the information from the manufacturer.
- 3.11. If there is insufficient stock, an order must be placed as early as practicable and contact Medicines@secamb.nhs.uk and Logistics to inform of the issue.
- 3.12. If the temperature cannot be resolved or there is a concern with the excursion duration, the MGT should be consulted via Medicines@Secamb.nhs.uk.
- 3.13. Medicine in quarantine should be labelled and separated in a plastic bag/box/crate away from the normal stock.
- 3.14. Specialist areas such as the Distribution centre and the stores centres are unmanned at night, at weekends and Bank Holidays. Any alert will likely breach the 6 hours and must be escalated to the Operations Manager or tactical for the area who will investigate.
- 3.15. All incidents raised that require medicines to be quarantined pending further action must have a DIF1 (Datix) incident form completed.

4. OSD closure

Courage,

& Integrity

4.1. If the OSD are closed or unmanned, all activity is passed to Emergency Operation Centre Managers (EOCMs) who are to follow Appendix G until the OSD is manned again, whereby they resume responsibility.

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5. Automated temperature monitoring failure

- 5.1. In the event of a complete system failure, it will be necessary to monitor temperatures using the back-up temperature monitoring system located adjacent to the Monika sensor in each area.
- 5.2. Refer to the SOP on Manual Temperature Monitoring.
- 5.3. Monika Customer Service must be contacted immediately on 01664 420 022 and a Datix (DIF1) form submitted.

6. Yearly Calibration and Servicing

- 6.1. Yearly calibration is completed by Monika. The medicines team in SECAmb are responsible for maintaining location records and ensuring recalibration occurs.
- 6.2. As part of the recalibration and service process, Monika replace the batteries in any sensors.
- 6.3. Locations and times must be considered as Monika technicians will need access to the medicine rooms. An OTL will need to be onsite to enable and oversee this process.

7. Monika Faults

- 7.1. If there is an alert that is not a temperature excursion, Monika needs to be contacted immediately by the duty OTL on 01664 420022 and press the number for technical support.
- 7.2. If the fault is related to our IT or network, a Marvel request must be completed. This will then generate a ticket that SECAmb IT are responsible for completing. Monika will be called and a job number for the incident collected and recorded on the Marvel request.
- 7.3. These faults must not alter the recording of the temperature. If you are unable to see the temperature through the system, the manual temperature monitoring SOP should be followed. If the temperature recording is not being completed, the escalation process above should be followed.
- 7.4. Time Outs are an example an IT network fault and manual monitoring should commence immediately until the issue is fixed and live temperature monitoring confirmed via the Monika web site.





7.5. Once an OTL has confirmed the system is operational, the Marval ticket can be closed.

8. Weekly Audit

- 8.1. The Monika Web client should be checked weekly as part of the medicines audit. The Daily Diary should be reviewed to ensure all alerts have been appropriately dealt with before being signed off and that names have been entered for all staff involved (see Appendix E).
- 8.2. All signed-off reports will be saved in theReports area of the system and can be viewed at any time (see Appendix F).
- 8.3. Weekly checks will also form part of the Operational Unit Manager (OUM) monthly report.
- 8.4. Any time(s) a temperature excursion Datix is raised, it needs to be reported into the Medicines Governance Group (MGG) via operations for review and assurance of governance processes.

9. Email maintenance

- 9.1. SECAmb and Monika emails have been established for the reporting of alerts. These emails must be updated with any changes to email distribution lists or changes to staff.
- 9.2. The emails from Monika are sent to "temperature.station name@secamb.nhs.uk". If a station moves or opens, then this email address should be created immediately so any escalations are received.
- 9.3. A Marval ticket must be created then forwarded by email to: temperature.medicineshq@secamb.nhs.uk, MRCM, OTL emailing group, OUM and OM. The Marval must specify that the email address needs to receive external emails in order for the alerts and notifications to work.

10. Opening and Closing Sites

- 10.1. Incorporating a new site is a cost to the Trust and the devices need to be installed and calibrated. When a site is opened or closed, Monika must be contacted by MGT if medication will be stored there.
- 10.2. Monika requires a one-month notice period for any new installations, or a three-month notice period for any sites that are closing.
- 10.3. The cost and calibration time(s) need to be considered for any opening and/or closing of the sites.



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- 10.4. The management of Monika sits with the MGT in SECAmb. They can be contacted via medicines@secamb.nhs.uk.
- 10.5. **Opening new sites:**
- 10.5.1. A risk assessment must be conducted to determine the best location for the Monika probe, considering any windows, heaters or air conditioning units in the area (Appendix H).
- 10.5.2. The MGT will determine whether there are any spare sensors present at Paddock Wood MDC, or whether a new sensor needs to be ordered.
- 10.5.3. The MGT will then contact Monika and arrange for an engineer to visit the new site and install the equipment.
- 10.5.4. An email address will be required for new sites as outlined in the 'email maintenance' procedure above.
- 10.6. Closure of sites:
- 10.6.1. If reopening a pre-existing site after temporary closure, the base units can be reinstalled at no charge to the Trust. However, the unit(s) need to be the same device(s) and cannot be taken from another decommissioned site. If new units or devices are required, a cost to the Trust will be incurred.
- 10.6.2. If a site is closing, the MGT must be informed three months in advance to initiate the decommissioning process.
- 10.6.3. The MGT will then contact Monika to alert them of the site closure.
- 10.6.4. Estates will remove the sensors that are no longer required and send them to Paddock Wood MDC for storage.

11. Definitions

- 11.1. Datix is the Trust's incident management system.
- 10.4. DIF1 is the report process used by Datix

12. Responsibilities

12.1. The **Chief Executive Officer (CEO)** is accountable for Medicines use and governance in the Trust





- 12.2. The **Chief Medical Officer** through delegation by the CEO, has overall responsibility for medicines governance system design and overall assurance. The Executive Medical Director has responsibility for the implementation, review, and thus revision where required, of this procedure.
- 12.3. The **Chief Pharmacist** is the professional medicines governance lead for the Trust and is responsible for producing robust systems and processes which comply fully with legislation, national guidance, and regulatory requirements to ensure the safe and effective management and use of medicines throughout the Trust. The Chief Pharmacist supports the Chief Medical Officer and Executive Director of Operations providing pharmaceutical professional advice with regards to all medicines related policies, procedures and practices.
- 12.4. The **Executive Director of Operations**, through delegation by the CEO, has overall responsibility for the implementation, operation and local assurance of this policy. The Executive Director of Operations has overall responsibility for holding his/her staff to account for any deviations from this policy and is responsible for the operational compliance of this procedure.
- 12.5. The Executive Director of Operations, Chief Medical Officer and Chief Pharmacist are responsible for escalating unresolved concerns to the Medicines Governance Group (MGG).
- 12.6. The Executive Director of Operations delegates local responsibilities and accountability for this procedure to the **Associate Directors of Operations**, **Operational Unit Managers**, **Operational Managers**, **Specialist Managers** and where relevant the **Head of Fleet and Logistics**.
- 12.7. The Associate Directors of Operations, Operational Units Managers, Operational Managers, Specialist Managers and where relevant the Head of Fleet and Logistics delegate their local responsibility and accountability for this policy to their staff including the Operational Team Leaders (OTLs), Logistics Manager, and others.
- 12.8. The **Executive Director of Nursing and Quality** has responsibility for matters relating to regulatory compliance, risk management, health and safety relating to this procedure.
- 12.9. Controlled Drug Accountable Officer is also the Chief Medical Officer and is responsible for the safe management and use of Controlled Drugs within the Trust along with co-operating and sharing information relating to concerns about the Trust's use and management under the Controlled Drug (Supervision of Management and Use) Regulations 2013. These





- responsibilities include keeping records of the investigation of concerns and acting where appropriate.
- 12.10. The **Medicines Safety Officer (MSO)** supports local medication error reporting and learning. The MSO acts as the main contact for NHS England and Medicines and Healthcare Products Regulatory Agency (MHRA).
- 12.11. The **Medicines Governance Group (MGG)** is responsible, for providing strategic direction for the implementation of medicines management and practice within the Trust The primary objective of MGG is to ensure appropriate clinical and cost effective use of medicines, promoting the highest standards of medicines management and safe practice throughout the Trust, by ensuring that senior managers are aware of issues relating to the use of medicines within the organisation as part of the overall clinical and corporate governance structure.
- 12.12. The role of The **Non-Medical Prescribing (NMP) Group** is to provide overarching multidisciplinary leadership for non-medical prescribing (NMP) within the Trust. In doing so, it manages the process of Trust approval to train as a non-medical prescriber and to prescribe, taking account of service redesigns and improved patient access to medicines. The NMP Group aims to strengthen and monitor the governance issues associated with non-medical prescribing, to determine potential and support existing non-medical prescribers, advise the MGG on matters relating to non-medical prescribing and will report exceptions relating to non-medical prescribing to the MGG.
- 12.13. The **Medical Gas Subgroup** provides assurance to MGG that medical gases are effectively monitored and managed within the Trust.
- 12.14. The **Patient Group Direction (PGD) Approval and Working Group** provides assurance to MGG and ensures the development, review, updates and implementation of PGDs are in line with legislation and national good practice.
- 12.15. The **Medicines Governance Team (MGT)** are responsible for ensuring the safe and efficient procurement of medicines, including controlled drugs to ensure the quality of the product, safe dispensing/packing into medicines pouches through to safe disposal of pharmaceutical waste. The MGT will support the Chief Pharmacists with drug shortages, drug alerts and relevant information relating to medicines is communicated in a timely manner.
- 12.16. **All staff** are responsible for their own professional practice. All staff involved in the prescribing, supply, dispensing, handling, storage, administration and disposal of medicines, including controlled drugs, must receive appropriate training and assessment of competence before





commencing their roles. All staff who handle medicines are personally accountable for complying with this policy and relevant standard operation procedures, for reporting any concerns and for the safe handling of all medicines.

13. Education and Training

13.1. Formal training on the use of the automated temperature system was provided by Monika Smart Wireless Monitoring to senior members of the Operations Staff. This then was cascaded to all staff in their teams.

14. Audit and Review (evaluating effectiveness)

- 14.1. Operational Team Leaders (or other delegated local managers) must complete Weekly and Monthly Medicines Security and Storage Audits on the central database to ensure compliance with this SOP.
- 14.2. Deviations from this SOP must be investigated within 24 hours and corrective action taken to obtain full compliance by the next audit.
- 14.3. Concerns arising from any audit that cannot be locally resolved and full compliance assured by next audit must be escalated to the Executive Director of Operations, Chief Medical Officer and Chief Pharmacist via a DIF1 report.
- 14.4. Any unexplained loss of medicines or repeated deviation from SOP must also be reported via a DIF1.
- 14.5. The Chief Pharmacist and staff will periodically review the Weekly, Monthly Medicines Security and Storage Audits to ensure compliance with this SOP.
- 14.6. The Chief Pharmacist and staff will complete Quarterly Medicines Security and Storage Audit and report any repeated deviations or other concerns to the Medicines Governance Group.
- 14.7. Deviations arising from these inspections must be escalated to the Executive Director of Operations, Executive Medical Director and Chief Pharmacist via a DIF1 report.
- 14.8. All procedures have their effectiveness audited by the responsible Management Group at regular intervals, and initially six months after a new policy is approved and disseminated.





- 14.9. Effectiveness will be reviewed using the tools set out in the Trust's Policy and Procedure for the Development and Management of Trust Policies and Procedures (also known as the Policy on Policies).
- 14.10. This document will be reviewed in its entirety every three years or sooner if new legislation, codes of practice or national standards are introduced, or if feedback from employees indicates that the policy is not working effectively.
- 14.11. All changes made to this procedure will go through the governance route for development and approval as set out in the Policy on Policies.

15. Associated Trust Documentation

15.1. The Medicines Policy

16. References

- 16.1. Health Guidance: The temperature Requirements for Medicines Storage Publication code HCR-0213-076 February 2013.
- 16.2. Interim Report of Monitoring the Temperature of Medicines Project 2015, National Ambulance Service Medical Directors.
- 16.3. MHRA guidance on temperature compliance October 2016
- 16.4. Royal Pharmaceutical Society Guidance on the safe and secure handling of medicines December 2018

17. Financial Checkpoint

17.1. This document has been confirmed by Finance to have no unbudgeted financial implications.

18. Equality Analysis

18.1. The Trust believes in fairness and equality, and values diversity in its role as both a provider of services and as an employer. The Trust aims to provide accessible services that respect the needs of each individual and exclude no-one. It is committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.





18.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature then for the duration of the contract, the contractor or supplier would itself be considered a public authority and have the duty to comply with the equalities duties when carrying out those functions.





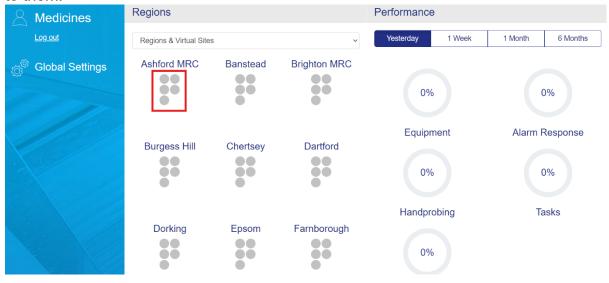
Appendix A: Monika login and site selection

Monika log in: Monika



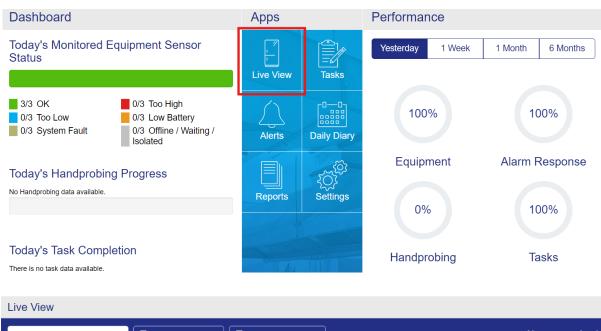
Site selection: click the highlighted bubbles under the site you wish to view.

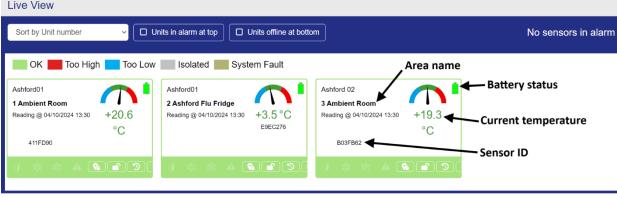
Please note: this screen will only appear for areas that have multiple sites assigned to them.





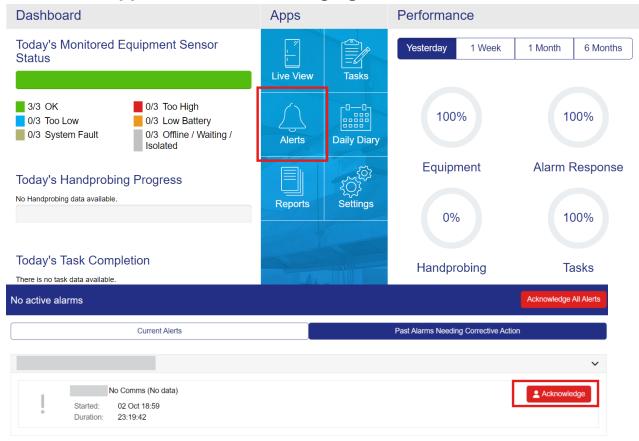
Appendix B: Live Monitoring Views





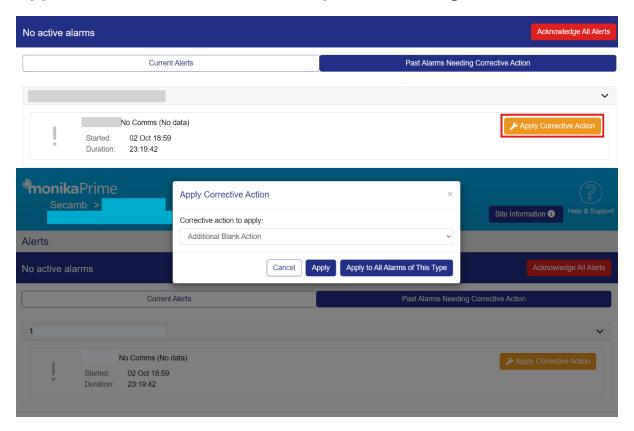


Appendix C: Acknowledging of Monika Alerts

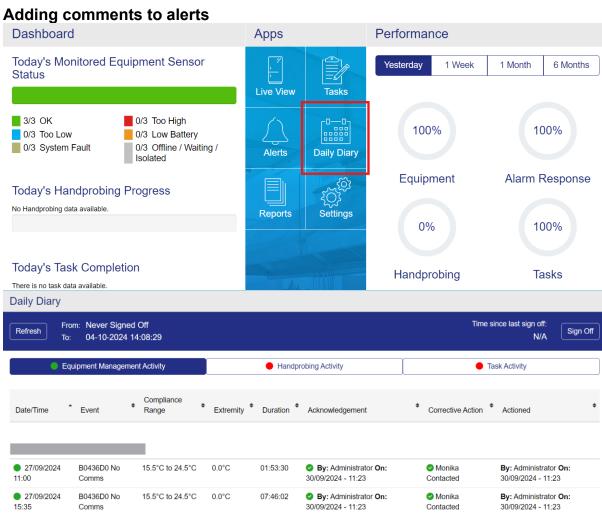




Appendix D: Corrective Action Required following Alerts





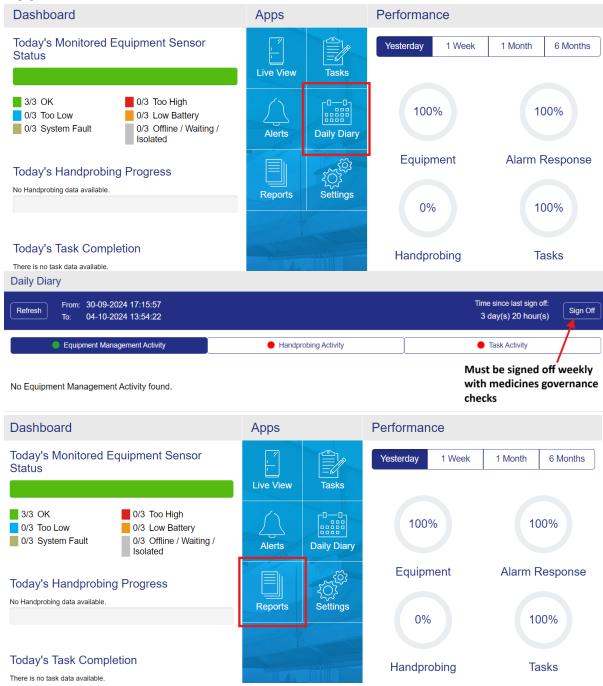


Add Preventive Action

Add Comment

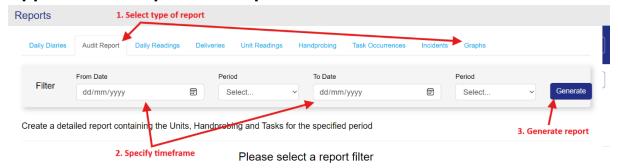


Appendix E: Critical Event Information





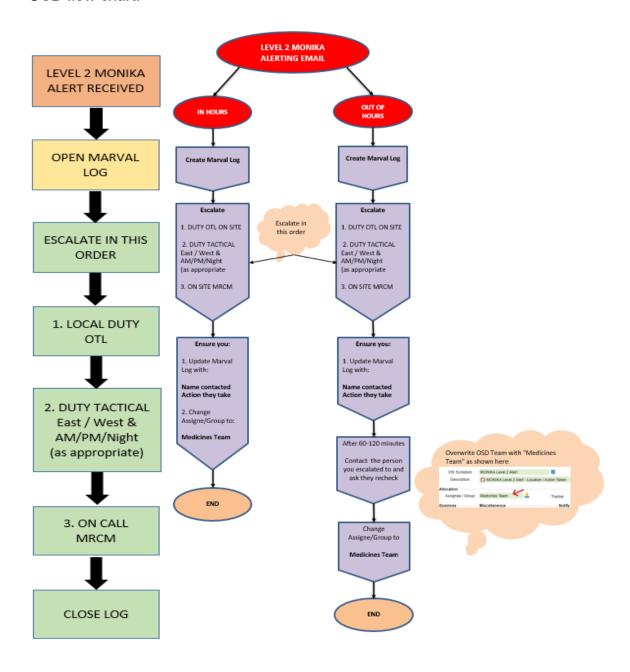
Appendix F: Graphs and Reports





Appendix G: OSD Flow Chart (Out of Hours Process)

OSD flow chart:





Appendix H: Risk Assessment

Monika Sensor Unit Details										
Area code						Name				
Short Name				Sensor SN						
Isolated	YES NO		Station or location Name							
Approximate Sp	ace Dir	mensi	ons							
Width	m	netres Length			metres Height			metres		M ³
Comments										
Are Heating / Cooling Devices room	in	Yes	No	Comments: Are they manual or controlled by a thermostat? Auto / Manual				o/		
Is there a windo the room.	w in	Yes	No	dire	nich ction t face?	stored in secondar		Are the pouches stored in a secondary cabinet?	Yes	No
Distance of cabinet/pouch from the sensor			metres							
Is there a backu	p temp	eratu	re monit	oring s	ystem i	n place.			Yes	No
Is the manual to	•		•						Yes	No
On observation could any devices or equipment within the room when switched ON or OFF adversely affect the pouches. Consider them being close to the source of heat or cold, in relation to the sensor. Comment:										
How many alarms have occurred in last 24 months. Have corrective action been implemented to address any potential recurrence?										
Has the previous 24 months temperature trends identified any seasonal risks?										
Refrigerators ONLY										
Model			Ser Nu	ial mber				No. of shelves		
Date last Serviced or Calibrated										
Are shelves loaded correctly, ensuring good airflow around se content?						nsors and		YES	N	0
Is the fridge the correct size for the maximum predicted contents?								YES	N	0
How many alarms have occurred in the last 12 months? YES NO								0		
Has the previous 24-month temperature trends identified any seasonal risks?							0			
Form completed by: Signature: Date:										





Form reviewed by:	Signature:	Date:
Form reviewed by:	Signature:	Date:

After a Risk review of the data provided the followir	ng Risk Rating has been assigned:
RED – Required immediate action to control temperature Amber – Action required with 60 days to control intermi Green – No Further Action Required.	
Final Action Approved by:	Chief / Deputy Chief Pharmacist
Addition Comments and Datix number:	