



Manual Medicines Temperature Monitoring in the event of a failure in the automated temperature monitoring system Standing Operating Procedure

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1 Scope

- 1.1. South East Coast Ambulance Service (SECAMB) NHS Foundation Trust is committed to safe and secure management of medicines and providing high quality patient care.
- 1.2. This procedure is applicable to all clinicians in the Trust and sets out the scope of clinical practice to which clinicians 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 may pose a potential risk to the health and wellbeing of the person receiving the medicine.
- 1.5. Medicines should be stored under conditions which ensure that 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.
- 1.7. All areas where medicines are stored the temperature should be monitored on a daily basis recording the actual temperature and the maximum and minimum temperature over the previous 24 hours.
- 1.8. The Trust has purchased an automated 24-hour medicines temperature monitoring system (MONIKA) which is first line option. However, the purpose of this procedure is to instruct staff how to monitor and record the temperature of the areas where medicines are stored in the event of a failure of the automated temperature monitoring system.
- 1.9. This SOP can be used to manually record temperatures in areas that are waiting for the automated system to be installed.

2 Procedure

- 2.1. A thermometer must be placed in every room or area including the medicines refrigerator where medicines are stored.



- 2.2. The thermometer must be able to register the current temperature as well as the maximum and minimum temperature of the storage area.
- 2.3. The thermometer must be read once every day and the minimum and maximum temperatures for the last 24 hours must be recorded on the Trust approved temperature monitoring log. (**See appendix A and B**).
- 2.4. If the refrigerator temperature is outside of the required range of between **2°C to 8°C** or the room temperature is outside of **15°C and 25°C** you must inform your station / senior manager immediately who should then inform the medicines governance team for further advice.
- 2.5. When the temperature has been recorded, where applicable ensure the thermometer is reset according to the refrigerator user manual. (**See Appendix C** for manual thermometers and **Appendix D** for digital thermometer).
- 2.6. If medicines are, or have been frozen (<0°C), medicines must not be re-used. Quarantine the medicines so they cannot be used. Inform your station / senior manager immediately who should then inform the medicines governance team for further advice. Use another refrigerator until the issue is rectified for any replacement stock.
- 2.7. If medicines are or have been exposed to prolonged heat (>25°C), medicines must not be re-used. Inform your station / senior manager immediately who should then inform the medicines governance team for further advice. Quarantine the medicines in a safe and secure area until further advice is received.
- 2.8. If additional stock is required as a result of a temperature deviation contact the store that supplies your medicines.
- 2.9. A DIF1 (Datix) incident form must be completed for any breach of temperature regardless whether it involves a refrigerator or a medicines room.

3 Escalation Procedure

- 3.1. All deviations from the quoted temperature range for medicines should be reported to the Medicines Governance Team via the medicines emails Medicines@secamb.nhs.uk stating the location of the medicines, the temperature and how long it has been out of range. A copy of the temperature log should be attached.



- 3.2. The Medicines Governance Team should:
 - 3.2.1. Contact the staff at the relevant location and establish what medicines have been affected, ensure there is sufficient stock of medicines remaining at the location or advise the staff to place an urgent order from their stores.
 - 3.2.2. Confirm with the staff the affected medicines have been quarantined so they cannot be used.
 - 3.2.3. Contact the manufacturer for advice on the suitability of use ensuring they are given the full facts i.e. storage temperature and duration.
- 3.3. The Chief Pharmacist or senior member of the Medicines Governance Team should be consulted before disseminating or acting on the information from the manufacturer.
- 3.4. If the medication can be used, the Medicines Governance Team inform the staff at the affected location to release the stock from quarantine and place in the general stock.
- 3.5. If the stock cannot be used the Medicines Governance Team will instruct the staff to place the stock in a blue lidded waste bin, seal the bin, complete a drug transfer waste form listing the contents and attach to the outside of the bin which should then be returned to Paddock Wood store by logistics for disposal.
- 3.6. Confirm a DIF1 has been completed (see 2.9).

4 Definitions

- 4.1. Datix is the Trust's incident management system.

5 Responsibilities

- 5.1. The **Chief Executive Officer (CEO)** is accountable for medicine use and governance in SECAMB.
- 5.2. The **Executive Director of Operations**, through delegation by the CEO, has overall responsibility for the implementation, operation and local assurance of this procedure. The Executive Director of Operations also has overall responsibility for holding their staff to account for any deviation from this procedure.
- 5.3. The Executive Director of Operations delegates local responsibility and accountability for this procedure to the **Regional Operation Managers (ROMs), Operational Unit Managers (OUMs),**



Operational Managers (Oms), Specialist Managers and where relevant the **Head of Fleet and Logistics**.

- 5.4. The ROMs, OUMs, OMs, Specialist Managers and where relevant the Head of Fleet and Logistics delegate local responsibility and accountability for this procedure to their staff including the **OTLs, Logistics Manager**, and others.
- 5.5. The **Executive Medical Director** has responsibility for all aspects of the safe and secure management of Controlled Drugs (CDs) at SECAMB.
- 5.6. The Executive Medical Director is the Trust's Controlled Drugs Accountable Officer (CDAO).
- 5.7. The **Chief Pharmacist** supports the Executive Medical Director and Executive Director of Operations providing professional advice with regards all medicines related procedures and practices.
- 5.8. The Chief Pharmacist delegate's local responsibility for Medicines Governance practice to their staff.
- 5.9. The Executive Director of Operations, Executive Medical Director and Chief Pharmacist escalate unresolved concerns to the Medicines Governance Group.
- 5.10. The **Executive Finance Director** through delegation by the CEO, has overall responsibility for Security and Estates. Their security and estates staff provide professional advice to the Chief Pharmacist, Executive Medical Director and Executive Director of Operations for the safe and secure handling of medicines in the Trust.
- 5.11. **All staff** who handle medicines are personally accountable for complying with this SOP, for reporting any concerns and for the safe and secure handling of all medicines.
- 5.12. The **Medicines Governance Group** are responsible for the monitoring of this procedure.

6 Audit and Review (evaluating effectiveness)

- 6.1. Operational Team Leaders (or other delegated local managers) must complete Weekly, Monthly Medicines Security and Storage Audits on the central database to ensure compliance with this SOP.
- 6.2. Deviations from this SOP must be investigated within 24 hours and corrective action taken to obtain full compliance by the next audit.



- 6.3. Concerns arising from any audit that cannot be local resolved and full compliance assured by next audit must be escalated to the Director of Operations, Medical Director and Chief Pharmacist via a DIF1 report.
- 6.4. Any unexplained loss of medicines or repeated deviation from SOP must also be reported via a DIF1.
- 6.5. The Chief Pharmacist and staff will periodically review the Weekly and Monthly Medicines Security and Storage Audits to ensure compliance with this SOP.
- 6.6. 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.
- 6.7. Ad hoc inspection of medicines security and storage will take also place as part of the Crime Reduction Surveys and Quality Assurance Visits.
- 6.8. Deviations arising from these inspections must be escalated to the Director of Operations, Medical Director and Chief Pharmacist via a DIF1 report.
- 6.9. 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.
- 6.10. 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).
- 6.11. 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.
- 6.12. All changes made to this procedure will go through the governance route for development and approval as set out in the Policy on Policies.

7 Associated Trust Documentation

- 7.1. The Medicines Policy
- 7.2. Standing Operating Procedure for Automated Medicines Temperature Monitoring



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References

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



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Equality Analysis

- 9.1. 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.

- 9.2. 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: Medicines Refrigerator Temperature Monitoring Log

Appendix A Medicines Refrigerator Temperature Monitoring Log

Location of Fridge..... Month.....
Year.....

Procedure

1. The medicines refrigerator should be recorded **every** day to ensure the medicines are stored appropriately. The refrigerator temperatures should be between **2°C and 8°C**.
2. Record the temperature indicated on the refrigerator thermometer on the form below
3. If the refrigerator temperature is outside temperature range (between 2°C to 8°C) inform your station / senior manager **immediately** who should then inform the medicines governance team for further advice.
4. When the temperature has been recorded, where applicable ensure the thermometer is reset according to the refrigerator user manual.
5. If medicines are, or have been frozen (<0°C), medicines must not be re-used. Inform your station / senior manager **immediately** who should then inform the medicines governance team for further advice. Use another refrigerator until the issue is rectified for any replacement stock.

DATE	TIME	CURRENT TEMP (°C)	MINIMUM TEMP (°C)	MAXIMUM TEMP (°C)	SIGNATURE	ACTION TAKEN
1 st						
2 nd						
3 rd						
4 th						
5 th						
6 th						
7 th						
8 th						
9 th						
10 th						
11 th						
12 th						
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23 rd						
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25 th						
26 th						
27 th						
28 th						



29 th						
30 th						
31 st						



Appendix B: Medicines Store Areas Room Temperature Monitoring Log

Appendix B Medicines Store Areas Room Temperature Monitoring Log

Location Month..... Year.....

Procedure

The temperature the medicines are stored at should be recorded **every** day to ensure they are stored appropriately. Room temperature should be between **15°C and 25°C**

Record the temperature indicated on the thermometer on the form below

If the temperature is outside the temperature range stated above inform your station / senior manager **immediately** who should then inform the medicines governance team for further advice.

When the temperature has been recorded, where applicable ensure the thermometer is reset according to the user manual.

DATE	TIME	CURRENT TEMP (°C)	MINIMUM TEMP (°C)	MAXIMUM TEMP (°C)	SIGNATURE	ACTION TAKEN
1 st						
2 nd						
3 rd						
4 th						
5 th						
6 th						
7 th						
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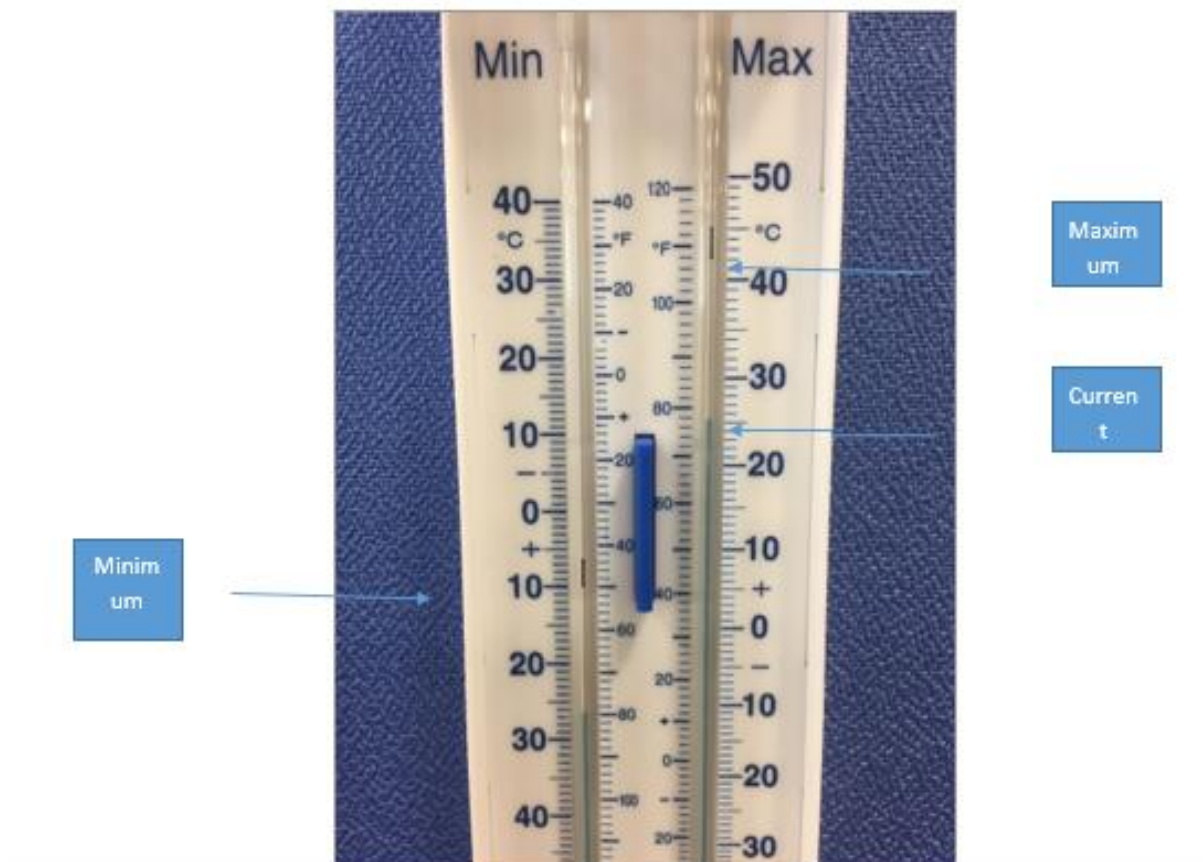
Appendix C: Temperature Reading using the Min/Max Thermometer

TEMPERATURE READING USING THE MIN/MAX THERMOMETER.

The thermometer should be securely mounted vertically (to enable the unit to be reset after each reading) on a wall out of direct sunlight.

Readings are to be taken at the agreed intervals and should be read from the **BOTTOM** of the bar **BEFORE** pressing (and holding) the blue reset button to allow the bar to return to the mercury. If the marker fails to fall back, gently tap the side of the unit while pressing the button.

The three required are i) Minimum ii) Maximum and the iii) Current temperature readings.





Appendix D: Temperature Reading using the Digital Min/Max Thermometer

A digital thermometer may also be used similar to this model below. Readings of maximum, minimum and current temperature should be taken and recorded as above. Once the readings have been recorded then the thermometer should be reset

