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

Contents

1. Scope

1.1. South East Coast Ambulance Service (SECAmb) NHS Foundation Trust (the 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. Exposure to temperatures below 0°C will freeze most medicines and carries a significant risk of causing irreversible damage. Freezing may also cause hairline fractures on the glass.

1.6. Low temperature exposure may precipitate or solidify the medicine. Precipitation may not be reversible, so these medicines need to be protected from routine low excursions of any duration.

1.7. 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.

1.8. 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.

1.9. 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.

1.10. The Trust has purchased an automated 24-hour medicines temperature monitoring system (MONIKA) which is the 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.

1.11. 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 current, maximum and minimum temperatures for the last 24 hours logged on the Trust approved temperature monitoring log. Ensure the date and time of the recording is also noted. (**See appendix A and B**)

The required temperature ranges are:

- **2°C - 8°C** Refrigerated Medicines
- **15°C - 25°C** Store Room (ambient) Medicines

2.4. If any of the recorded temperatures are outside of the required ranges, you must inform your station Operational Team Leader (OTL), Operational Unit Manager (OUM) or senior manager immediately, who should then contact the Medicines Governance Team for further advice and guidance around next steps required. If out of hours, see the section below titled “out of hours”.

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

- **Appendix C** for manual thermometers
- **Appendix D** for digital thermometer

2.6. **Refrigerated Medicines**

2.6.1. The following action must be taken for refrigerated medicines which are, or may have been, frozen or stored below <0°C for 15 minutes.

2.6.2. Immediately quarantine, removing from ‘live’ stock. Ideally remove to another refrigerator clearly marked ‘Quarantined stock. DO NOT USE’.

2.6.3. Inform your station OTL, OUM or senior manager immediately who should then contact the Medicines Governance Team for further advice and guidance around next steps required.

2.6.4. Use another refrigerator until the issue is rectified for any replacement stock.

2.6.5. Implement appropriate action to avoid reoccurrence.

2.6.6. A Datix (DIF1) detailing the medicines involved, the number of affected medication and temperature reached (including the duration outside of range) is to be completed.

2.7. **Store Room Medicines**

2.7.1. The following action must be taken for room stored (ambient) medicines which are or have been exposed to temperatures >25°C for 1 hour.

2.7.2. Immediately quarantine, removing from 'live' stock. Ideally remove to safe, secure location, clearly marked 'Quarantined stock. DO NOT USE'.

2.7.3. Inform your station OTL, OUM or senior manager immediately who should then contact the Medicines Governance Team for further advice and guidance around next steps required.

2.7.4. Implement appropriate action to avoid reoccurrence.

2.7.5. A Datix (DIF1) detailing the medicines involved, the number of affected medication and the temperature reached (including the duration outside of range) is to be completed.

3. Escalation Procedure

3.1. In the event of a temperature excursion where corrective action has not maintained adequate temperature levels, the Medicines Governance Team (MGT) must be contacted for advice on the stability and suitability of the medicines.

3.2. If medicines are, or have been, frozen (<0°C), medicines must not be re-used. Quarantine the medicines so they cannot be used and separated from the live stock. Inform your station / senior manager immediately. Use another refrigerator until the issue is rectified for any replacement stock. Put in measures to avoid this from happening again. Inform logistics and medicines so the stock can be removed from circulation and returned to Paddock Wood.

3.3. If room-temperature (ambient) medicines are, or have been, exposed to prolonged heat (>25°C) or cold (<15°C), medicines must not be re-used. Inform your station / senior manager immediately. Quarantine the medicines in a safe and secure area until further advice is received. Put in measures to avoid this from happening again. Inform logistics and medicines so the stock can be removed from circulation and returned to Paddock Wood.

3.4. If there is urgent operational need to get advice on the medicines OOH, the medical oncall needs to be contacted immediately.

3.5. The medicines should be kept in the medicines room because it is temperature controlled and has the correct security measures. 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 medicines affected, the number of medicines, how long the excursion was and at what temperature. The investigation should establish why this occurred and what has been done to resolve the issue.

3.6. The time period where the temperatures was out of range needs to be included in the DIF1 and what the highest or lowest temperature was.

3.7. If the temperature is out of range for a prolonged period of time then the manufacturer of the medicines should be contacted by the MGT for advice on the suitability of their use and given the information about the temperature excursion.

3.8. The Chief pharmacist or senior member of the MGT should be consulted before disseminating or acting on the information from the manufacturer.

3.9. If there are insufficient stock, place an order immediately by contacting Medicines@secamb.nhs.uk and Logistics to inform them of the issue.

3.10. If the temperature cannot be resolved or there is a concern with the duration, the medicine team should be consulted via Medicines@Secamb.nhs.uk.

3.11. The MGT will advise on actions to take with the medicine in quarantine.

3.12. Medicine in quarantine should be separated from the normal stock in a plastic bag or crate and not mixed with normal stock.

3.13. Specialist areas such as the Distribution centre and the stores centres are unmanned at night, at weekends and Bank Holidays. Any alert will breach the 6 hours and be escalated to the Operations Manager or tactical for the area who will investigate.

3.14. All incidents raised that require medicines to be quarantined pending further action must have a DIF1 incident form completed.

4. Definitions

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

4.2. DIF1 is the report process used by Datix.

4.3. MONIKA – Is an automated 24-hour medicines temperature monitoring system use in SECAmb.

5. Responsibilities

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

5.2. 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.

5.3. 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.

5.4. 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.

5.5. The **Executive Director of Operations**, **Chief Medical Officer** and **Chief Pharmacist** are responsible for escalating unresolved concerns to the Medicines Governance Group (MGG).

5.6. 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.**

5.7. 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.

5.8. The **Executive Director of Nursing and Quality** has responsibility for matters relating to regulatory compliance, risk management, health and safety relating to this procedure.

5.9. **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.

5.10. 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).

5.11. 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.

5.12. 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.

5.13. The **Medical Gas Subgroup** provides assurance to MGG that medical gases are effectively monitored and managed within the Trust.

5.14. 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.

5.15. 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.

5.16. **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.

6. Audit and Review (evaluating effectiveness)

6.1. OTLs (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, Chief Medical Officer 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. Adhoc 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, Chief Medical Officer 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

8. 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

9. Financial Checkpoint

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

10. Equality Analysis

10.1. 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.

10.2. 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

Location …… 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
1st						
2nd						
3rd						
4th						
5th						
6th						
7th						
8th						
9th						
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Appendix B: Medicines Store Areas Room Temperature Monitoring Log

Location ……. Month…… Year……

Procedure

1. 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**
2. Record the temperature indicated on the thermometer on the form below
3.
4. 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**.**
5. 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
1st						
2nd						
3rd						
4th						
5th						
6th						
7th						
8th						
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Appendix C: Temperature Reading using the Min/Max Thermometer

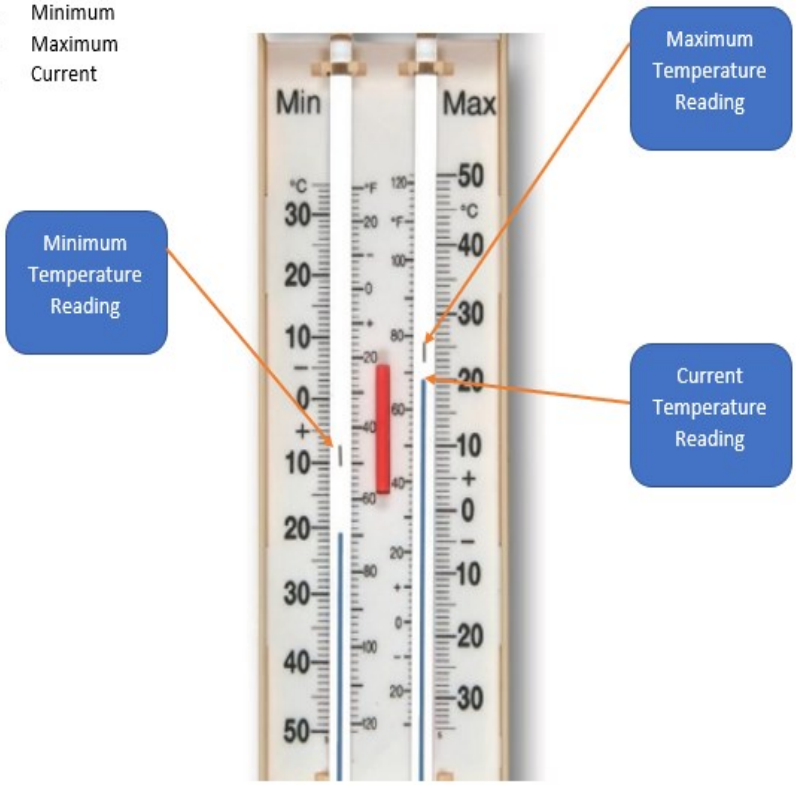
TEMPERATURE READING USING THE MIN/MAX THERMOMETER

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 (or red) reset button to allow the bar to return to the liquid. If a marker fails to fall back, gently tap the side of the unit while pressing the button.

The three temperatures readings required are:

I. Minimum
II. Maximum
III. Current



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.