

## Policy for the Monitoring of Temperatures for the safe storage of medicines on wards and departments

<b>Approved By:</b>	Policy and Guideline Committee
<b>Date of Original Approval:</b>	<b>3<sup>rd</sup> August 2018</b>
<b>Trust Reference:</b>	<b>B14/2018</b>
<b>Version:</b>	V3
<b>Supersedes:</b>	V2 – July 2020
<b>Trust Lead:</b>	Elizabeth McKechnie, Medication Safety Pharmacist
<b>Board Director Lead:</b>	Andrew Furlong, Medical Director
<b>Date of Latest Approval</b>	21 January 2022 – Policy and Guideline Committee
<b>Next Review Date:</b>	<b>March 2025</b>

## CONTENTS

---

Section		Page
1	Introduction and Overview	4
2	Policy Scope	4
3	Definitions and Abbreviations	4
4	Roles and Responsibilities	4
5	Policy Implementation and Associated Documents	6
6	Education and Training	9
7	Process for Monitoring Compliance	9
8	Equality Impact Assessment	9
9	Supporting References, Evidence Base and Related Policies	9
10	Process for Version Control, Document Archiving and Review	9

Appendices		Page
A	Fridge temperature instructions	10
B	Ambient (room) temperature instructions	11
C	Ambient temperature action plan	12
D	Fridge temperature guide	13
E	Freezer temperature guide	14
F	Ambient temperature guide	15

### REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

---

December 2021

Addition of information relating to use of freezers for medicines

Change to when data loggers are used.

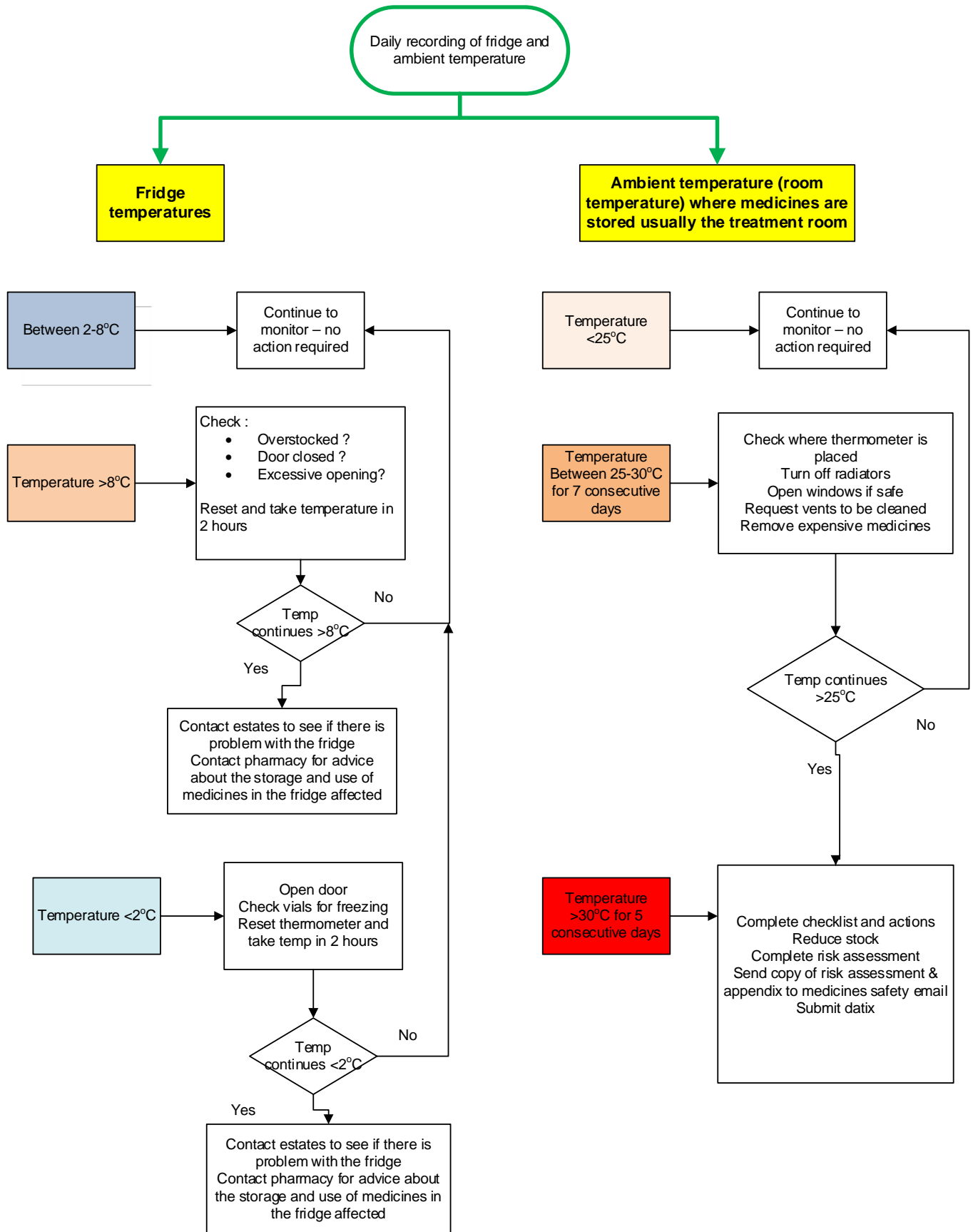
Reference that this policy does not cover the process in Pharmacy departments where a separate SOP is used.

### KEY WORDS

---

Temperature, fridge, monitoring, room temperature, medicines, Freezers

# Summary Flow chart



## 1 INTRODUCTION AND OVERVIEW

---

- 1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for monitoring the temperature where medicines are stored in treatment rooms and refrigerators in wards, departments, theatres and clinics with the exception of the pharmacy department. .
- 1.2 Medicines specify the required storage temperature on their packaging or labelling. For ambient (room) storage it is usually stated a maximum of 25°C or 30°C. Storage above the licensed temperature range may reduce the shelf life of the product, but the medicine is still likely to be fit for use. Medicines with ambient temperature storage are considered to be relatively robust and usually allocated a long shelf life, typically 2 years. There is limited if any evidence of direct harm due to medicines stored above the licensed temperature in hospitals, but harm cannot be excluded.
- 1.3 Medicines which are susceptible to degradation by high ambient temperatures over a shorter period have more stringent requirements e.g. store in a refrigerator and may have shorter shelf lives. The recommended storage temperature for Fridge items will be between 2°C and 8°C. A few medicines require storage in a freezer below -20°C
- 1.4 Medication must be stored in line with manufacturer recommendations to ensure the quality of the product up until administration to the patient. Medication storage facilities must therefore be maintained at appropriate temperatures to prevent degradation of the medicinal products and ensure the medication received by the patient is as intended by the manufacturer
- 1.5 It is essential that the temperature of ambient storage areas is monitored and action taken if temperatures are out of range. The impact of temperatures above the specified range is dependent on the temperature the medicine has been stored at and the length of time the temperature has been out of range. Short excursions out of range are unlikely to impact on expiry date.

## 2 POLICY SCOPE

---

- 2.1 This policy applies to all healthcare professionals in UHL who are involved in the supply, storage and administration of medicines in clinical areas.
- 2.2 This policy does not cover the storage of medicines in the pharmacy department. Please refer to Pharmacy SOP 233 Temperature Monitoring in UHL pharmacy departments.

## 3 DEFINITIONS AND ABBREVIATIONS

---

- 3.1 **Ambient** temperature is often call 'room' temperature
- 3.2 **Data Logger** – an electronic device which is placed in a treatment room and is set to record temperatures at regular intervals over a period of time. It is then placed in a USB port on a computer and the data downloaded.



## **4 ROLES AND RESPONSIBILITIES**

---

**4.1** The Executive Director with overall responsibility for this policy is the Medical Director.

**4.2 Clinical Management Group (CMG) Heads of Nursing are responsible for:**

- Ensuring all new and existing staff are made aware of this policy through local induction and other communication methods.
- Ensuring compliance with this policy.
- Ensuring that air cooling is considered in any new building or refurbishment of areas where medicines are stored.

**4.3 Ward/ department manager is responsible for :**

- Ensuring the thermometers are located appropriately e.g. in treatment rooms near medication storage areas but out of direct sunlight. A digital thermometer is recommended for recording ambient temperatures.
- Ensuring new staff are aware of their responsibility to monitor room and fridge / freezer temperatures where in use and explain the process of escalation.
- Ensuring daily checks are conducted by staff and the appropriate log is completed, including resetting of the fridge/freezer temperature. The check does not have to be a registered member of staff and can be undertaken by a housekeeper or HCA as long as they have been given adequate training and understand the need to escalate.
- Ensuring out of range temperatures are escalated as appropriate according to the criteria set out in the Policy and all possible actions are taken to reduce the ambient temperature where high.
- Ensuring thermometer batteries are changed as required and that new thermometers are ordered as needed to replace broken ones.
- Completion of an action plan ( see appendix C ) if ambient temperatures are out of range consistently above 30°C .
- Storing the temperature monitoring booklets for two years after completion.

**4.4 Individual staff are: -**

- To be aware of this policy and ensure medicines are received and stored appropriately in line with the manufacturers packaging and labelling conditions.
- Responsible for escalating temperatures which fall outside the usual range as detailed in this policy.
- Responsible for highlighting issues of faulty fridges / freezers or thermometers to the ward / departmental manager.

#### 4.5 Ward based pharmacy staff are responsible for:

- Carrying out spot checks on the documentation of daily refrigerator / freezer or room temperature checks.
- Responding to escalations and providing advice on which medicines are suitable to use when stored outside the parameters recommended by the manufacturer.
- Assisting Ward / departmental managers with actions to try and reduce the ambient temperature in the area
- Review stock lists and reduce stockholding further and consider removing medicines particularly sensitive to heat (for example liquids, short expiry medicines)

#### 4.6 Medicines Information Department is responsible for:

- Providing advice, supporting ward teams, on the suitability of products stored outside the parameters recommended by the manufacturer.

Note : Manufacturers are not required to provide information on the impact of storage outside the licensed temperature range and so for the majority of medicines limited information is available.

#### 4.7 Medicines Safety Team is responsible for:

- Providing support and advice to ward and pharmacy staff where there are issues with temperatures outside the usual range.
- Installing temperature data loggers to monitor new areas where the temperatures have been consistently high (over 30°C).
- Maintaining a log of wards/ departments where there is a risk due to temperatures outside usual ranges.
- Summarising and reporting the risk across the Trust annually to the Medicines Optimisation Committee

## 5 POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

---

- 5.1 Good practice requires that the storage areas for medicinal products are maintained within acceptable temperature limits and that these are monitored regularly to demonstrate that these conditions are met.
- 5.2 Ambient temperatures in areas where medicines are stored and fridge / freezer ( where applicable) temperatures must be recorded daily at ward / departmental level. Temperatures must be maximum and minimum temperatures for the last reporting period ie 24 hours.
- 5.3 Exceptions will be given to those areas where medications are stored but which close at weekend and Bank Holidays. In this situation, temperatures do not need to be recorded during department closures. The period of closure must be clear on the monitoring sheet

by entering the word 'closed' in the relevant section. Daily monitoring must resume when the department reopens.

5.4 The maximum / minimum temperatures must be recorded in the temperature log book on a daily basis and the column corresponding to the day of the recording signed by the staff member. Any data point outside the normal range must be escalated accordingly.

5.5 Temperature monitoring booklets are available from the print rooms. These booklets have space for ambient temperature and fridge temperature records. A separate book is available for freezers.

## 5.6 Ambient temperature monitoring

5.6.1 Digital Thermometers and replacement batteries must be ordered by the ward / department and used in treatment rooms where medicines are stored. The medicines safety team can give details on the current recommended thermometers in use in the trust. ( contact extn 12644 or via email [PharmacyMedicinesSafety@uhl-tr.nhs.uk](mailto:PharmacyMedicinesSafety@uhl-tr.nhs.uk) )

### 5.6.2 In range: temperatures less than 25°C

- If all temperature points e.g. maximum and minimum are below 25°C, then storage conditions are optimal. Continue monitoring daily.

### 5.6.3 Temperature recording over 25°C:

- Individual temperature deviations are unlikely to have a detrimental effect on medications overall.
- If the temperature reaches between 25°C and 30°C for seven consecutive days then
  - ❖ Report to the pharmacy clinical team for advice
  - ❖ Look at ways of reducing the temperature if possible – opening windows, moving stock, cleaning air vents
  - ❖ Consider reducing stock holding if possible and expiry of medicines
  - ❖ Avoid having staff huddles or meetings in the room as this can increase the ambient room temperature.

### 5.6.4 Temperatures recording over 30°C

- Temperatures continuously over 30°C may compromise the stability of medication stored in this area and action must be taken. If a temperature is recorded over 30°C for 5 consecutive days the clinical pharmacy team MUST be contacted.
- Complete the action plan in the temperature log. Sample see appendix C

5.6.5 **Actions to be taken** led by sister/charge nurse – please refer to appendix F

*Immediate actions include:*

- Check the thermometer is appropriately placed. It should be located near the medication storage areas and not over / near a direct heat source. If it is near a heat source move it to a more appropriate place.
- Open windows if possible whilst maintaining medication safe storage and security.
- Turn off all non-essential heat sources e.g. radiators.

*Medium term actions:*

- Ask facilities to clean air vents if not already done and ask if there is any air conditioning temperature control which can be switched on to reduce ambient temperature within the treatment room.
- Remove all items within three months of their manufacturer's expiry date if possible and replace with longer dated products. This may not be possible for some medicines which have short shelf lives.

*Long term actions:*

- If the temperature of the room is constantly above 30°C then :
  - Complete the checklist / action plan appendix C
  - Work with pharmacy to reduce stockholding further, and consider removing any items particularly sensitive to heat (e.g. liquids, short expiry medicines)
  - Remove expensive items and consider storing in an alternative place
  - Consider options to avoid using storage area e.g. sharing medicines storage area with an adjacent ward, move treatment room to a cooler area
  - Consider the option of permanent temperature control for the area. Liaise with the senior CMG team.

Add to the risk register if the temperature cannot be reduced in a defined time period.

5.6.6 Reduction in shelf life to be considered:

If medicines have an expiry of over a year there is no need to reduce the expiry as stock should be used within the time

The table is a guide to help consider the impact of temperature on medication shelf life

Storage range in SPC	Temperature reached	Length of time at high temp	Reduce the expiry on the pack by
25°C or below	25-30 °C	24 hours	2 days
	25-30 °C	1 week	2 weeks
	30-35 °C	24 hours	4 days
	30-35 °C	1 week	4 weeks
	35-40 °C	24 hours	8 days
	35-40 °C	1 week	8 weeks
30°C or below	30-35 °C	24 hours	2 days
	30-35 °C	1 week	2 weeks
	35-40 °C	24 hours	4 days
	35-40 °C	1 week	4 weeks

Stock rotation is important - consider removing short dated medicines to use in an area where the medicine is likely to be used.

## 5.7 Fridge monitoring

5.7.1 Maximum, minimum and current temperatures must be checked on a daily basis and recorded in the monitoring log. The fridge should be reset daily and the appropriate column in the monitoring log signed



5.7.2 If a log is made for any temperature outside the normal range then action must be taken. Items stored in the fridge are more prone to degradation than those stored at room temperature.

Actions to take ( also refer to appendix D) :

#### **Fridge temperature too high > 8°C**

- Ensure the door is firmly closed.
- Ensure the fridge is not over stocked. Over stocking fridges may cause a fridge to work less efficiently. Ask the pharmacy team to help remove excess stock and return/discard as appropriate.
- Establish whether the door been opened excessively over the last few hours, avoid this practice if possible.
- Reset the thermometer and recheck in two hours. Record the extra check in the comments section of the temperature monitoring book
- If after resetting the thermometer the temperature is still high, this may suggest that the fridge is faulty. Call Estates and log a call for the fridge to be reviewed.
- Contact pharmacy at the earliest opportunity within normal working hours for advice on how to manage the fridge stocks.
  - Medicines Information is available Monday-Friday 9am-5pm.
  - On call Pharmacist is available for fridge enquiries Saturday – Sunday 9am -5pm.
  - If overnight then please wait until the morning to contact the pharmacy team unless the medication is life critical and it is required for the patient imminently. In these instances call the on call pharmacist for advice.

#### **Fridge temperature too cold <2°C**

- If current temperature is less than zero then immediately open door to allow some warming. Check any liquid vials for evidence of freezing.
- Reset the thermometer and recheck in two hours. Record the extra check in the comments section of the temperature monitoring book
- Call Medicines Information (6491) for advice 9am-5pm. Outside these hours move stock to another fridge and call in the morning. If the medicine has not been frozen it is still acceptable to use.
- If the temperature remains too low then the fridge may be faulty. Medicines Information will advise on stock and whether the fridge needs reporting to Estates

### **5.8 Freezer monitoring**

5.8.1 Maximum, minimum and current temperatures must be checked on a daily basis and recorded in a separate freezer monitoring log book . The freezer thermometer should be reset daily and the appropriate column in the monitoring log signed

5.8.2 If a log is made for any temperature outside the normal range then action must be taken. Items stored in the freezer are prone to degradation once removed from a freezer and the expiry in use date will be considerably reduced.

Actions to take ( also refer to appendix E) :

#### **Freezer temperature too high > -18°C**

- Check the contents to establish if packages look like contents have defrosted. This may be difficult to determine.

- Quarantine possible affected stock in the freezer. Contact pharmacy at the earliest opportunity within normal working hours for advice on how to manage the freezer stocks.
  - Medicines Information is available Monday-Friday 9am-5pm.
  - On call Pharmacist is available for fridge enquiries Saturday – Sunday 9am -5pm.
- Ensure the door is firmly closed.
- Ensure the freezer is not over stocked. Over stocking freezer may cause a freezer to work less efficiently. Ask the pharmacy team to help remove excess stock and return/discard as appropriate.

If overnight then please wait until the morning to contact the pharmacy team unless the medication is life critical and it is required for the patient imminently. In these instances call the on call pharmacist for advice.

## **6 EDUCATION AND TRAINING REQUIREMENTS**

---

6.1 No additional training is required to support this policy.

## **7 PROCESS FOR MONITORING COMPLIANCE**

---

<b>Element to be monitored</b>	<b>Lead</b>	<b>Tool</b>	<b>Frequency</b>	<b>Reporting arrangements Who or what committee will the completed report go to.</b>
Temperatures recorded – spot audits	Medication safety pharmacist	Ward storage audit tool	Monthly	Medicines Optimisation Committee CMG Heads of Nursing
Number of ambient temperature areas regularly over 30 <sup>0</sup> C	Medication safety pharmacist	Log of reported areas & datix incidents	6 monthly	Medicines Optimisation Committee CMG Heads of Nursing

## **8 EQUALITY IMPACT ASSESSMENT**

---

- 8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
- 8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

## **9. SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES**

---

Leicester Medicines Code

Pharmacy SOP 233 Temperature Monitoring in UHL pharmacy departments.

## **10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW**

---

- 10.1 The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system.
- 10.2 This Policy will be reviewed every three years or sooner in response to clinical or risk issues.

.

There are different types of fridges and thermometers in the Trust and so not every thermometer will be covered by the guide below. If the thermometer is a different type and you are unsure how to reset or obtain readings please record the details and email to [PharmacyMedicinesSafety@uhl-tr.nhs.uk](mailto:PharmacyMedicinesSafety@uhl-tr.nhs.uk)

**The most common type has a Hi/Lo button:**



1. Press the Hi/Lo button
2. The maximum temperature is displayed initially followed by the minimum and then the actual
3. Once all the recordings have been documented press the Set button and record that this has been done in the temperature monitoring book

The thermometer below has been bought and used widely across the Trust. Other thermometers may be bought but must be able to record Min/ Max temperatures.

The min / max temperatures are automatically reset daily so no additional button has to be pressed.



### Fisher Scientific™ Traceable™ Big-Digit See-Thru™ Thermometers

Attach to the outside of a window to view outdoor temperatures. Fisher Scientific Traceable Big-Digit See-Thru Thermometers have transparent display with 1.25 in.H (3.1cm) digits which show current and minimum/maximum temperatures.

**Brand:** Fisher Scientific™

**Manufacturer Part Number:** 4160

THERMOMETER SEE THRU BATTERY OPERATED with traceable NIST certificate -25to 70degC, +/-

**UNSPSC:** 41112213

**Code:** 46

**Additional Details: Weight:** 1.00000kg

**Includes:** Velcro™ mounting tape, AAA battery

<b>Product Code.</b>	11892592
Quantity	
Price	
1	£37.95 / Each
<b>Qty</b>	<input type="text" value="1"/>
In Stock	8
<a href="#">Add to basket</a>	

## Ambient temperature action plan

Complete for all areas with temperatures consistently (5 or more days) over 30°C

Ward : ..... Site : ..... CMG:.....

Action	Notes	Result / observation
Ensure the thermometer is appropriately placed e.g. it is not over a radiator.	<i>Move it if necessary and begin monitoring again. It is not necessary to do a full action plan if the thermometer has been in an inappropriate position. Ensure this is placed in an area which will represent the storage conditions of the medication e.g. near a medication cupboard.</i>	
Review heat sources – radiators, windows, pipes etc. Can medication be moved to cooler location within the room? Will there be any estates work required to cool the room?	<i>Heat rises, therefore higher shelves may be hotter than lower shelves. Are blinds required for windows? Do pipes need lagging to reduce heat escape? Will there be any estate work required? If so then liaise with the ward/department leader to get this underway.</i>	
Is there any air conditioning available? Does the room have air vents	<i>Some rooms have air vents which help to cool the air flow. Confirm with Infection prevention that these can be used in the area. If so please contact facilities to clean these and ensure they are switched on.</i>	
Review the stock list. Obtain details on stock turn over for the area to ensure all lines are used within the timeframe highlighted above from the Q10 calculation e.g. frequently used items will have a higher turnover and so may be unaffected than less frequently used lines. Take remedial action to ensure the quality of medication stored in the area.	<i>Highlight any expensive items – consider if there are needed on the stock list or could be stored elsewhere. Consider enteral feeds and storage on the ward. Can some items be safely stored at 30°C (not always &lt;25°C from manufacturer) Remove all medication which is within 3 months of its manufacturer expiry date. Remove all medication that has <u>not</u> been stored in the original packaging as provided by the manufacturer e.g. strips of tablets, medication decanted into bottles, reconstituted medication e.g. antibiotics. Resupply as required. Review the stock list – can low turnover items be removed or stored elsewhere? The Chief technician for distribution and stores will have information on stock turnover</i>	
Complete a risk assessment and raise with the CMG team	<i>This will help to identify areas in the CMG which are unsuitable for medicine storage and prioritised in future work</i>	

Completed by : .....

Date: .....


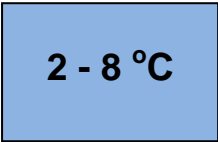
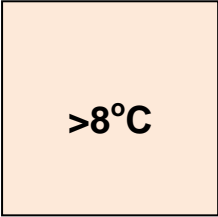
page 1

**Ambient temperature action plan**

*Complete for all areas with temperatures consistently (5 or more days) over 30°C*

Ward : ..... Site : ..... CMG:.....

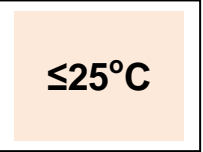

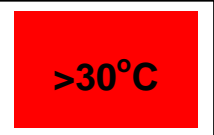
Review date	Observations	Actions taken	Completed by

Temperature	Actions
	<ul style="list-style-type: none"> <li>➤ Open door</li> <li>➤ Check vials/ ampoules for freezing. If frozen contact Medicines Information / Pharmacy for advice</li> <li>➤ Reset fridge temperature and take temperature again in 2 hours</li> <li>➤ If the temperature continues to be below 2°C contact : -                             <ul style="list-style-type: none"> <li>✓ estates to arrange for them to check the fridge</li> <li>✓ pharmacy for advice about which products can be used</li> </ul> </li> <li>➤ Identify another fridge to use if possible</li> </ul>
	<ul style="list-style-type: none"> <li>➤ Continue to monitor temperature daily, no action required</li> <li>➤ Ensure fridge is reset daily and recorded in temperature booklet</li> </ul>
	<ul style="list-style-type: none"> <li>➤ Check                             <ul style="list-style-type: none"> <li>➤ Is the door closed properly?</li> <li>➤ Is the fridge overstocked? - ask pharmacy staff to remove items</li> <li>➤ Has there been excessive opening for example the fridge being cleaned?</li> </ul> </li> <li>➤ Reset fridge temperature and take temperature again in 2 hours</li> <li>➤ If the temperature continues to be above 8°C contact : -                             <ul style="list-style-type: none"> <li>✓ estates to arrange for them to check the fridge</li> <li>✓ pharmacy for advice about which products can be used</li> </ul> </li> <li>➤ Identify another fridge to use if possible</li> </ul>



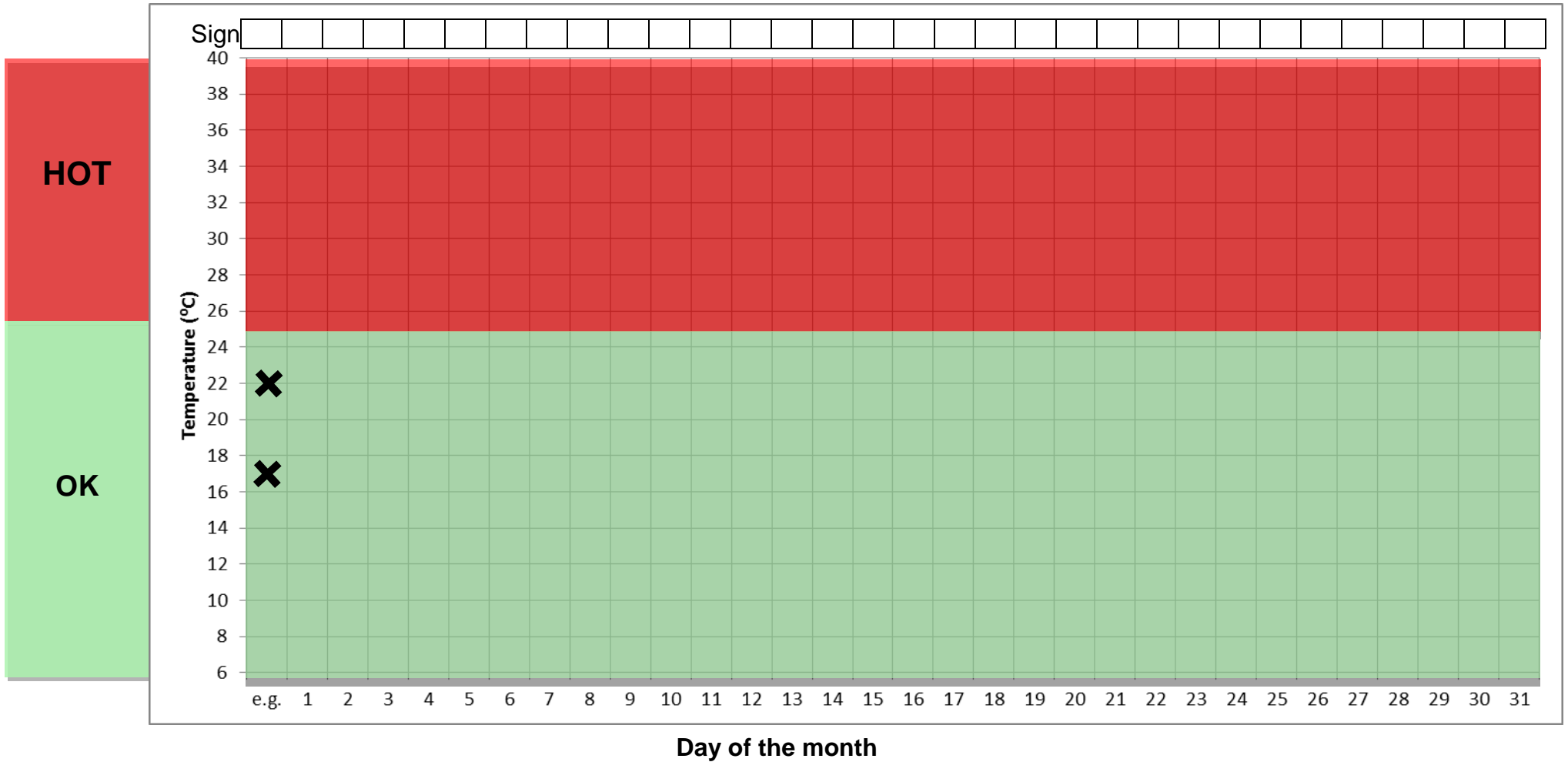
Temperature	Actions
<div data-bbox="172 488 389 659" style="border: 1px solid black; background-color: #ADD8E6; padding: 5px; text-align: center;"> <p><b>-25°C or below</b></p> </div>	<ul style="list-style-type: none"> <li>➤ Continue to monitor temperature daily</li> <li>➤ Speak to medicines information to understand if medicines are affected.</li> </ul>
<div data-bbox="172 716 389 932" style="border: 1px solid black; background-color: #FFDAB9; padding: 5px; text-align: center;"> <p><b>-17°C or above</b></p> </div>	<ul style="list-style-type: none"> <li>➤ Check             <ul style="list-style-type: none"> <li>✓ Is the door closed properly?</li> <li>✓ Is the freezer overstocked?</li> <li>✓ Has there been excessive opening?</li> </ul> </li> <li>➤ If the temperature continues to be -17°C or above contact : -             <ul style="list-style-type: none"> <li>✓ estates to arrange for them to check the freezer</li> <li>✓ pharmacy for advice about which products can be used</li> </ul> </li> <li>➤ Identify another freezer to use if possible</li> </ul>

## Ambient temperature guide

Temperature	Actions
	<ul style="list-style-type: none"> <li>➤ Reset thermometer and continue daily recording of max/ min temperatures</li> <li>➤ no action required</li> </ul>
	<ul style="list-style-type: none"> <li>➤ Check where the thermometer is placed. Remove from direct sunlight</li> <li>➤ Turn off radiators, lagging for pipes</li> <li>➤ Open windows if safe to do so ensuring that medicines are still stored securely</li> <li>➤ Request air vents to be cleaned by estates and switched on. Check with infection Prevention to confirm safe to use in area.</li> <li>➤ Check if air conditioning or air flow options are available</li> <li>➤ If remains over 25°C for 7 days or more contact : -               <ul style="list-style-type: none"> <li>❖ the pharmacy team</li> <li>❖ look at reducing stock holding</li> </ul> </li> <li>➤ Continue to monitor temperatures</li> </ul> <p><b>Pharmacy team</b> to review stock – remove expensive medicines and those with a shelf life less than 3 months where possible.</p>
	<p>If temperatures &gt; 30°C for 5 days or more</p> <ul style="list-style-type: none"> <li>➤ Complete the checklist and actions</li> <li>➤ Complete risk assessment</li> </ul> <p><b>Pharmacy team</b></p> <ul style="list-style-type: none"> <li>✓ to review stock – remove expensive medicines and those with shelf life less than 3 months</li> <li>✓ Reduce stock holding where possible – look at stock turnover, usage</li> <li>✓ Consider other alternative storage – shared with another ward, other suitable cupboards?</li> <li>✓ Look at mechanism for reducing expiries as necessary as stock is sent to the area.</li> </ul> <p>In areas known to be constantly above 30°C then review actions taken every 3 months.</p>

**Medicines Room Temperature Monitoring Record**  
Record the min and max temperatures as shown below.  
If outside green range TAKE ACTION.

Month:



In the example above the temperature range was MIN: 17°C, MAX: 22°C



