

ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

PROCEDURE FOR MONITORING THE TEMPERATURE
OF DRUG STORAGE AREAS

1. INTRODUCTION

- 1.1. Medicines must be stored according to the manufacturer's requirements and away from direct sunlight, heat source or moisture. For most medicines this is below 25°C, although some specify storage in a "cool dry place" or below 15°C, and others require refrigeration between 2° and 8°C.
- 1.2. The storage conditions form part of the marketing authorisation and storing a product outside the manufacturer's recommendations renders its use 'unlicensed'. Where items are stored outside the required conditions the stability and/or efficacy of the product will be affected and the product may no longer be fit for use.
- 1.3. In order to provide the necessary level of assurance, the temperature of areas used to store drugs, including refrigerators and emergency drugs cupboards, should be monitored and recorded on a **daily** basis.
- 1.4. Working days are defined as days when staff are present and in a position to monitor temperatures. Where the term "daily" is used this means on working days.

2. STORAGE AT ROOM TEMPERATURE

- 2.1. Rooms used for the storage of medicines must be maintained below 25°C. In order to ensure that this is the case, the ambient temperature needs to be monitored on a daily basis. Where air conditioning is installed this must be switched on at all times and set to a temperature between 22° and 24°C.
- 2.2. Items requiring storage in a "cool dry place" or below 15°C must be stored under these conditions or otherwise in a fridge.

Top Tips

Where the ambient temperature is repeatedly measuring above 25°C and no air conditioning is installed, take the following simple measures:

- Turn off radiators and computer equipment, if practical
- Put shading on windows to reduce heat from direct sunlight
- Look at the location of fridges and other heat sources
- If windows can be safely opened without risking security, and the outside air is cooler than the room temperature, open the window.

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- 2.3. If the ambient temperature persists above 25°C contact the estates department for advice on temperature solutions. Estates staff may ask for copies of the completed Temperature Monitoring Form so that they can see the detail of the temperatures being experienced.
- 2.4. Pharmacy staff can provide advice on using medicines which are experiencing prolonged exposure to high temperature.
- 2.5. Medicines requiring storage at room temperature should not be stored in a refrigerator during hot weather as this also results in medicines being stored outside the manufacturer's requirements and renders their use 'unlicensed'.

3. REFRIGERATED STORAGE

- 3.1. Medicines that require refrigeration usually need to be stored at a temperature between +2° and +8°C and this will be clearly marked on the outer carton or bottle. In order to ensure that the refrigerator is operating correctly, the temperature needs to be monitored on a daily basis.
- 3.2. Most of the drug products requiring fridge storage will not deteriorate significantly if they are kept out of a fridge for short periods, e.g. during transport between the pharmacy and the ward. This includes items such as insulin, lorazepam injection and some antibiotic liquids and eye drops. If an item is left out of the fridge for any period or the fridge is found to be outside the range of +2° and +8°C advice must be sought from the pharmacy department.
- 3.3. Certain products must be maintained at fridge temperature at all times or their efficacy cannot be guaranteed. For such products, a 'cold chain' must be maintained whenever the products are in transit, by using approved pharmaceutical cool bags and associated cool packs. This includes Risperdal Consta® injection and most vaccines.

4. MONITORING AND RECORDING TEMPERATURES

- 4.1. Ward/Unit Managers must ensure that named members of staff are responsible for carrying out this monitoring, and that these staff fully understands how to make the measurements and record them. Staff should also be trained to ensure that they know what action to take if a temperature reading falls outside the permitted range, and in respect of refrigerators of the need to defrost the drug fridge on a regular basis.
- 4.2. Readings should be made on a daily basis using a **digital maximum-minimum thermometer**. Some modern drug fridges come with an integral digital maximum-minimum thermometer (Pharmacy can advise on the purchase of these), but most have a simple dial thermometer built into the door. This type of thermometer is not suitable for temperature monitoring, and sites with this type of fridge will need to purchase a separate digital maximum-minimum thermometer in addition to the built-in thermometer. This is because the temperature inside the body of the fridge, particularly where

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there are densely packed medicines, can vary from that in the door or the top or bottom of the fridge. The built-in thermometer may not pick up this temperature variation, and may not provide minimum and maximum readings.

- 4.3. The maximum-minimum thermometer has a probe which can be inserted into the body of the fridge by passing the cable through the seal on the hinged side of the door. The thermometer unit can then be placed on top of the fridge so that readings can be taken without needing to open the door.
- 4.4. Most digital maximum-minimum thermometers measure both the ambient (room) temperature and the temperature of the probe. This type is preferred as one thermometer can be used for both sets of reading.
- 4.5. The probe (remote) temperature reading needs to be recorded for the refrigerator. The thermometer shows the maximum and minimum temperatures reached within the fridge since it was last reset, and these are the readings that need to be recorded – they must remain within the range **+2° to +8°C**. It is essential that the thermometer is **reset** after each daily reading is taken.
- 4.6. A list of pharmacy fridges and a recommended maximum/minimum thermometer can be found on INPUT by searching “refrigerators”. This includes ePROC codes.
- 4.7. A monthly temperature monitoring sheet is available as Annex 1.
- 4.8. It is important that where the temperature is outside the required range a comment is added to show what action has been taken. Completed sheets must be signed off by the ward/unit manager and should be retained for 2 years.

Tips for Taking Accurate Readings

- Ensure the probe is in a suitable position – it should not be touching the interior walls of the fridge, the ice compartment or any of the contents.
- Ensure that the body of the thermometer is in a suitable position – it should not be close to a radiator or other heat source, or in a draught from a window or air-conditioning unit.
- Make sure that the staff who are responsible for monitoring the fridge and room temperatures know how to take the daily readings and reset the thermometer.
- The 'reset' button must be pressed after recording the daily maximum and minimum temperatures, in order to obtain a new baseline.
- If the readings are the same every day, it suggests that the thermometer is not being reset on a daily basis – small day-to-day variations in maximum and minimum temperatures are normal, provided they remain within the range +2 ° to +8° C for the refrigerator and below 25°C for the room temperature.
- Investigate any readings that fall outside the permitted ranges. If investigation confirms that the readings were taken correctly, contact pharmacy for advice about whether the refrigerator or drug cupboard contents can still be used. Check that the refrigerator is working correctly – if not, transfer the contents to another fridge until it can be repaired or replaced. Complete a Datix form.
- Ensure that the fridge is defrosted and cleaned regularly, e.g. monthly, and that the contents are stored in a suitable place during defrosting.
- If the fridge is not likely to be required for storing any medications for an extended period, it should be turned off rather than run empty. It should be defrosted and cleaned in the usual way, and then stored with the door held ajar rather than closed.

TEMPERATURE MONITORING FORM

ACTIONS TO BE TAKEN IF TEMPERATURE OUTSIDE RANGE

| | | |
|---------------|--|---|
| FRIDGE | | <ul style="list-style-type: none"> Move affected stock to a working fridge (i.e. running between 2°C and 8°C) in a bag labelled 'DO NOT USE'. Contact pharmacy for advice on the stability of the fridge items See overleaf for things to check if the temperature is outside 2°C and 8°C Contact EBME / ALTHEA (formally TBS) to request same day maintenance categorising the job as High Priority Submit a Datix incident report detailing the actions taken |
| | | <ul style="list-style-type: none"> Keep the door closed and reset the thermometer. Monitor hourly until between 2°C and 8°C, resetting the thermometer after each reading. If temperature does not return to normal within 2 hours follow steps above. |
| | | <ul style="list-style-type: none"> Monitor temperature DAILY |
| ROOM | | <ul style="list-style-type: none"> Record clinic room temperature DAILY. If it exceeds 25°C on a regular basis contact pharmacy for advice and submit a Datix incident report detailing the actions taken. |

READINGS MUST BE TAKEN DAILY (UNLESS WARD / CLINIC UNMANNED)

| Ward/Unit: | | FRIDGE (join min and max recorded temperatures with a line) | | | | | | | | | | | Year: 20__ | Month: | ROOM Max. Temp °C | Thermo- meter(s) Reset (✓) | Checked by (initials) | Action taken if outside range (See above) |
|------------|------|--|-----|-----|---------|-----|-----|-----|-----|-----|-----|------|------------|--------|-------------------------|----------------------------------|-----------------------------|--|
| Date | Time | 0°C | 1°C | 2°C | 3°C | 4°C | 5°C | 6°C | 7°C | 8°C | 9°C | 10°C | | | | | | |
| Example | | | | | ●-----● | | | | | | | | 23.1°C | ✓ | AB | | | |
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SAMPLE - DO NOT USE

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| Ward/Unit: | | Year: 20__ | | | | | | | | | | Month: | | | | |
|------------|------|--|-----|-----|-----|-----|-----|-----|-----|-----|-----|-------------------------|----------------------------------|-----------------------------|--|-----------|
| Date | Time | FRIDGE (join min and max recorded temperatures with a line) | | | | | | | | | | ROOM Max. Temp °C | Thermo- meter(s) Reset (✓) | Checked by (initials) | Action taken if outside range (See above) | |
| | | ≤ 0°C | 1°C | 2°C | 3°C | 4°C | 5°C | 6°C | 7°C | 8°C | 9°C | | | | | ≥ 10°C |
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IF FRIDGE TEMPERATURE FALLS OUTSIDE +2°C to +8°C CHECK THE FOLLOWING

- Has the fridge been disconnected / turned off or has there been a power cut? If the power supply to the fridge is broken report this immediately to ward/unit manager
- Has the fridge door been left open?
- Has the fridge been opened frequently in the last few hours?
- Is the thermostat set too high or too low (if applicable)?
- Was the thermometer reset correctly after the last reading?
- If used, is the thermometer probe correctly placed inside the fridge?
- Is the fridge more than half full?
- Does the fridge need defrosting (if applicable)?
- Has the thermometer been accidentally damaged, e.g. fallen off the fridge?
- Does the fridge need servicing?

If in doubt remove the affected stock and place it in bags labelled 'DO NOT USE' and store in a properly working refrigerator. Seek advice from pharmacy about whether the stock can be used.

END OF MONTH REVIEW

| | Yes | No |
|---|-----|----|
| Has the room temperature been checked every day? * | | |
| Has the fridge temperature been checked every day? * | | |
| Has the fridge been defrosted? Insert date | | |
| Has any action been necessary due to the temperature being out of range If yes, give details | | |
| Date of last service | | |

| | |
|------------------------------|--------------|
| Reviewed by (Manager) | Date: |
|------------------------------|--------------|

RECORD TO BE RETAINED ON THE WARD FOR 2 YEARS

* excluding weekend and public holidays if the site is closed

SAMPLE - DO NOT USE