# Trust Standard Operating Procedure

University Hospitals Plymouth NHS Trust

## SAFE STORAGE OF REFRIGERATED MEDICINES (INCLUDING TEMPERATURE MONITORING)

| Issue Date | Review Date | Version |
|---|---|---|
| May 2019 | May 2024 | 1 |

### Purpose

The Purpose of this Standard Operating Procedure is to provide Trust employees guidance and operating procedure in the safe and correct management of medicines which require refrigeration, including the storage of medicines, sourcing specified (pharmaceutical grade) refrigerator equipment and the correct monitoring of refrigerator/freezer temperatures.

### Who should read this document?

All clinical staff working in environments where medicines are required to be stored in refrigerators.

### Key Messages

To ensure all staff are aware of procedures to maintain correct storage conditions for refrigerated medicines to prevent degradation of the medicine resulting in the loss of activity and\or the formation of toxic breakdown products. And where breaches from the required temperature have occurred, staff are aware of the correct process for escalating the breach.

| Core accountabilities | |
|---|---|
| **Owner** | Medicines Safety Officer |
| **Review** | Medicines Governance Committee and noted by Pharmacy Board |
| **Ratification** | Medical Director |
| **Dissemination (Raising Awareness)** | Heads of Nursing<br>Pharmacy |
| **Compliance** | Heads of Nursing |

| Links to other policies and procedures |
|---|
| Medicines Management Policy version 10.4 (located in Trust documents via Document Library) |

| Version History | | |
|---|---|---|
| **1** | May 2019 | New SOP |

*The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.*

**An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.**

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

# Standard Operating Procedure for medicines refrigerator use including the monitoring and recording refrigerator temperature

## 1 Introduction

This Trust wide SOP provides guidance on how staff should manage medicines which are required to be stored in the 'cold chain', the approved refrigerator equipment, the temperature monitoring requirements and what to do in the event the refrigerator temperature is outside the recommended range (+2 to +8°C).

## 2 Definitions

1. Medicines Refrigerator (Pharmaceutical Grade):

Dedicated medicines refrigerators should be of a suitable standard to keep medicines at the correct temperature. The following refrigerators can be ordered via Pharmacy (plh-tr.Pharmacy-Qc@nhs.net) if required:

a) PPGR158UK -LHH Under-counter Control Plus Glass Door Refrigerator 158L - Lec Medical

b) https://www.lec-medical.co.uk/product/vaccine-refrigerator-glass-door-273l-ppgr273uk-2-2/

c) https://www.lec-medical.co.uk/product/pharmacy-refrigerator-glass-door-444l/

d) https://www.lec-medical.co.uk/product/large-pharmacy-refrigerator-600l-glass-door/

2. Medicine Refrigerator Thermometer:

**Fisherbrand™ Traceable™ Refrigerator/Freezer Thermometers** have been approved for use within the organisation.

When a new thermometer is required, please contact Pharmacy plh-tr.Pharmacy-Qc@nhs.net

## 3 Regulatory Background

To maintain stability of product a range of medicines are required to be refrigerated and maintained between the temperatures +**2 and +8 °C.**

To find out if a product needs to be stored in the refrigerator, information can be found:

- On product packaging
- Patient Information Leaflet (PIL) within product packaging or
- The electronic Medicines Compendium (eMC) on the internet (manufacturers information)

Compliance is required by the Trust and CQC.

## 4 Key Duties

a) All areas are responsible for ensuring the medicine refrigerators are secure and accessible only to authorised staff.

b) Do not store food or biological samples in medicine refrigerators.

c) The refrigerator must be kept in a well-ventilated position away from heat sources.

d) The refrigerator must be serviced annually, sooner if the refrigerator is compromised, such as moving or re-siting the refrigerator. Annual maintenance must include temperature gauge calibration and portable appliance testing (PAT).

e) To avoid accidentally interrupting the electricity supply, either use a switchless socket or clearly label the plug with a cautionary notice, for example: “Do not unplug/switch off”.

f) To ensure adequate air flow and prevent temperature breaches in the refrigerator do not store large amounts of medicines.

g) Expiry date checks, cleaning, defrosting and stock rotation of refrigerator contents must be completed each month.

## 5 Procedure to Follow

**Recording the Temperature:**

a) Record the refrigerator temperature daily (all clinical refrigerators and freezers need to be monitored every 24 hours or during normal working hours).

b) Record a minimum, maximum and current refrigerator temperature using the approved minimum/maximum thermometer.

c) Record the temperatures (current, minimum and maximum readings) on the database http://temperaturemonitoring. For instructions on how to do this please see appendix 1.

d) Reset the thermometer after each reading (see appendix 2). If you do not have the Fisherbrand thermometer, please refer to the manufacturer’s instructions or contact Pharmacy QC plh-tr.Pharmacy-Qc@nhs.net (must be able to read minimum and maximum temperature)

e) Ensure the thermometer probe cable does not interfere with the refrigerator door seal resulting in the temperature breach.

**If the refrigerator/freezer is recording out of range (temperature breach):**

a) If the refrigerator is out of the +2 to +8 °C temperature range, ensure the door is kept closed and recheck after 15 minutes and again after 30 minutes.

b) If the refrigerator remains out of range after 30 minutes, and it is clear the temperature is not returning to the normal range, all stock must be relocated to a different medicines refrigerator for quarantine - Label items 'DO NOT USE'

c) Report to the Estates team - faulty

d) Notify your line manager at earliest opportunity during working hours.

e) During out of hours contact the Senior Nurse on 0355 for authorisation to quarantine stock. When out of hours make a record and handover to contact Estates.

f) Contact Pharmacy Quality Control (QC) to identify stability and alternative storage (ext 37452).

g) Complete breach form (appendix 3) and send to Pharmacy QC inbox: plh-tr.Pharmacy-Qc@nhs.net

h) Make a note of the following information for QC:

   i. The drugs in the refrigerator (including manufacturer and batch number)

   ii. When the refrigerator was last working correctly – this information is on the thermometer

   iii. The current temperature

i) Complete a Datix form.

## 6 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed and ratified by the Medicines Governance Committee including the Medical Director, Chief Pharmacist and Chief Nurse and noted at the Pharmacy Board.

Non-significant amendments to this document may be made, under delegated authority from the Chief Pharmacist, by the nominated author. These must be reviewed and ratified by the Medical Director and should be reported, retrospectively, to the Medicines Governance Committee and noted at the Pharmacy Board.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments,

informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

## 7 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Medical Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

## 8 Monitoring and Assurance

- All healthcare practitioners are responsible for ensuring medicinal products are stored in accordance with the patient information leaflet, summary of product characteristics and in accordance with instructions on the label. The patient information leaflet and/or summary of product characteristics document for UK licensed medicinal products may be found at www.emc.medicines.org.uk
- The healthcare professional with overall responsibility for the area in which the drugs are stored is responsible for the safekeeping (including access) of medicines.
- The person who receives a delivery of medicines is responsible for checking the contents of delivery against the order and signing to authorise receipt of the delivery. This person is also responsible for unpacking any refrigerated items immediately, putting them away in the medicines refrigerator and ensuring the refrigerator is closed correctly.
- A nominated member of the ward/departmental team is responsible for the monitoring the medicines refrigerator temperature on a daily basis and ensuring appropriate actions are taken when temperatures breach safe parameters (+2 to +8 $^{o}$C) or in the event of a refrigerator breakdown.
- Failure to record/monitor the refrigerator on a daily basis will be reported to Heads of Nursing weekly within the summary produced by Performance Information team.
- Datix incidents will be monitored by Heads of Nursing at monthly 1:1 service line performance reviews and reported to Pharmacy Quality Management Group (PQMG) and NMOC. Action plans will be implemented as required.
- Audit of refrigerator temperature monitoring processes will be recorded on Meridian, integrated into Nursing audit. Reported to NMOC.

## 9 Reference Material

Please see the following references:

https://www.cqc.org.uk/guidance-providers/adult-social-care/medicines-requiring-refrigerator-storage

https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

Controls Assurance Standard – Medicines Management (Safe and Secure Handling), Department of Health (Oct 2001).

Medicines Code Chapter on Temperature Monitoring of Medicinal Products
Medicines and Health Regulatory Agency (MHRA) guidelines on 'Control and monitoring or storage and transportation temperatures of medicinal products'

'The safe and secure handling of medicines, A team approach; Royal Pharmaceutical Society of Great Britain' March 2005

National Patient Safety Agency Alert on Vaccine Cold Storage (January 2010)

CQC KLOE Safe /legislative compliance S4 KLOE, Regulation 12

### Electronic processes and records

- Please see links below to refrigerators and thermometer which can be ordered via Oracle procurement system
- PPGR158UK -LHH Under-counter Control Plus Glass Door Refrigerator 158L - Lec Medical
- https://www.lec-medical.co.uk/product/vaccine-refrigerator-glass-door-273l-ppgr273uk-2-2/
- https://www.lec-medical.co.uk/product/pharmacy-refrigerator-glass-door-444l/
- https://www.lec-medical.co.uk/product/large-pharmacy-refrigerator-600l-glass-door/

| **Appendix – How to** record the refrigerator temperatures (current, minimum and maximum readings) on the database | **Appendix 1** |
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- Click on link for access to the database http://temperaturemonitoring.
- Locate your ward area by using the drop down menu
- Select the correct refrigerator
- Enter the current, minimum and maximum readings
- Click add when ready to submit data
- Confirm ‘Reset Thermometer’ has been completed by ticking box
- Repeat the process above for any additional refrigerators
- Once action complete close tab by clicking on X in temperature monitoring window
- If the refrigerator temperature is outside of the range of +2℃ and +8℃ then please complete the ‘Action Taken’ field on the temperature database and refer to guidance above in section: ‘**If the refrigerator/freezer is recording out of range’** on page 5.

| Appendix – Instructions for the Fisherbrand™ Traceable™ Refrigerator/Freezer Thermometer | Appendix 2 |
|---|---|

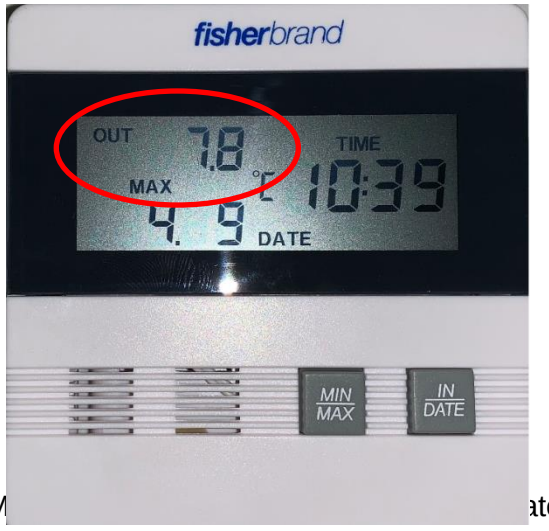
**Fisherbrand Traceable Thermometer with glycerol bottle probe.**

- When you receive your thermometer the date and time will have been pre -set. The out temperature will be displayed on the top left of the display – this is the current temperature of your refrigerator (diagram 1).

  Diagram 1


- To view the maximum temperature of the refrigerator click the MIN MAX button **ONCE** and ensure the display is showing OUT MAX (diagram 2). After recording the temperature press the IN DATE button once to reset (this will be signified by dashes appearing instead of the temperature being displayed)

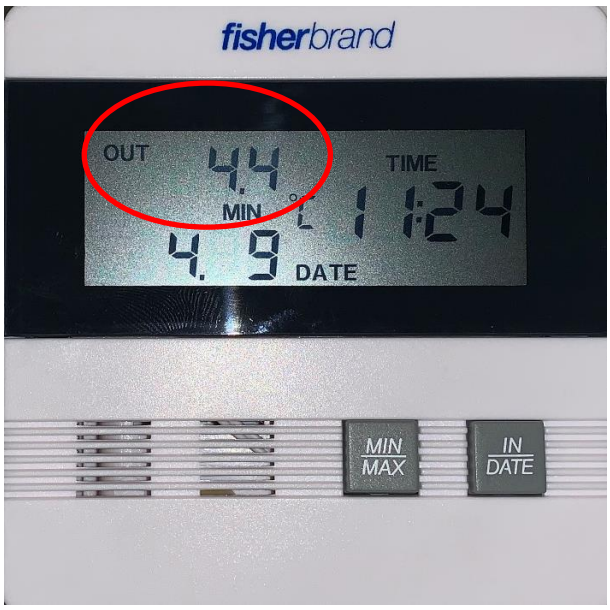
  Diagram 2



- To view the minimum temperature of the refrigerator click the $\frac{\text{MIN}}{\text{MAX}}$ button once and ensure the display is showing OUT MIN (diagram 3) After recording the temperature press the

  $\frac{\text{IN}}{\text{DATE}}$ button once to reset (this will be signified by dashes appearing instead of the temperature being displayed)

  Diagram 3




- To return to current temperature click $\frac{\text{MIN}}{\text{MAX}}$ button **THREE TIMES**.

| **Appendix - Refrigerator temperature breach information request** | **Appendix 3** |
|---|---|

Please complete this form and return to Pharmacy Quality (plh-tr.Pharmacy-QC@nhs.net). The suitability of use of each of the items listed will reviewed on receipt of the form. Please note that in many cases the use of such products once stored outside the recommended temperature range is considered “off licence”.

Any products exposed to a temperature breach should be clearly marked to indicate this breach.

| **Hospital Site and Department** | **Contact Name** | | **Contact details (tel /email** | | |
|---|---|---|---|---|---|
| | | | | | |
| | **Date** | **Time** | **Temperature** | | |
| | | | Min. | Current | Max. |
| **Current readings** | | | | | |
| **Maximum/minimum readings when breach detected (outside range +2 to +8°C)** | | | | | |
| **Last recorded readings between +2 to +8°C (before breach)** | | | | | |
| **Duration of temperature breach (if known)** | | | | | |

| **Drug Name, Form & Strength** | **Manufacturer** | **Batch number** | **Quantity** | **Any previous temp breach?** |
|---|---|---|---|---|
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Estates or the relevant service department should be contacted to check that the refrigerator is functioning correctly.