Medicine Storage and Temperature Monitoring

Standard operating procedure (SOP) | PHM-SOP-001

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Title	Medicine Storage and Temperature Monitoring
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Next review	{{document.review_date}} (12 months, or sooner after any incident or change)
Replaces	Replaces the earlier short form
Standards and criteria supported	Standard 3, criterion 3.1 (non-negotiable)
Evidence basis	E-009
Status of this document	Recommended best-practice model. A hospital may adopt, adapt or replace it with an equivalent that meets the same criteria.

At a glance: what to do

1. Store medicines in the dedicated medicine fridge at the temperature on the product label.
2. Read the fridge thermometer twice each working day and record it on PHM-FRM-001.
3. If the temperature is out of range, quarantine the stock at once and tell the pharmacist.
4. Never use quarantined medicine until the pharmacist releases it in writing.
5. The pharmacist reviews the log every week and signs it.

Stop and get help straight away if: the temperature is out of range and the pharmacist cannot be reached, or the fridge has failed with no working backup.

1. Purpose

To keep medicines and vaccines at the temperature their manufacturers require, so that they remain safe and effective, and to act at once when that temperature is not maintained [EC].

2. Scope

Applies to	All staff who store, check, prepare, or supply medicines and vaccines
Locations	All medicine and vaccine storage at {{facility.legal_name}}, including ward fridges, clinic fridges, emergency kits and transport boxes
When	At all times; daily readings; on any fault; on delivery of stock
Does not apply to	Controlled medicines security, which is covered by PHM-FRM-002 and the controlled medicines SOP

3. Definitions and abbreviations

Term	Meaning in this SOP
Storage temperature range	The range printed on the product label or the manufacturer's information (for example 2 to 8 degrees C for many refrigerated products). The label governs.

Term	Meaning in this SOP
Excursion	Any reading outside the storage range
Quarantine	Keeping stock separate, labelled "DO NOT USE", until the pharmacist decides
Min-max thermometer	A thermometer that records the lowest and highest temperature since it was last reset

4. Background and rationale

Many medicines and vaccines lose potency or safety if stored outside the required temperature. Temperature failures often go unnoticed because nobody checks the record. A daily reading and a fast response to an out-of-range reading are the controls.

This SOP is the method for criterion 3.1: the fridge temperature log (last 3 months) is the audit evidence. Controlled medicines are recorded separately (PHM-FRM-002).

5. Responsibilities

Role	Duties in this SOP	Competence needed
Pharmacist in charge	Owns the storage standard; reviews excursions; releases or destroys quarantined stock; signs the weekly review	Clinical pharmacy competence
Ward or department head	Makes sure readings are recorded twice daily and faults are reported	Trained in this SOP
Nurse or clinician who uses medicines	Checks the stock is stored correctly; reports any excursion or fault at once	Trained in storage rules
Facilities manager	Repairs faults; provides backup power or a backup fridge	Maintenance competence

6. Equipment, materials and resources

Item	Specification or standard	Check before use
Medicine fridge	Dedicated; no food or drink; temperature display or thermometer at the centre of the fridge, not at the door	Working; door seals intact
Thermometer (min-max or data logger)	Calibrated as the hospital schedule sets (EC); reset after each reading	Readings visible; battery working
Temperature log (PHM-FRM-001)	Current version; filled in at the same times each day	Available at the fridge
Backup fridge or cool box	Set up for the hospital fault plan (EC)	Checked monthly

7. Safety and infection prevention

- Do not store food, drink or specimens in the medicine fridge.
- Do not put medicines in the fridge door or on the fridge floor, where temperatures vary.
- Wear gloves when handling stock from quarantine if the product is damaged or leaking.

8. Before you start

- Check the fridge is working and the thermometer shows a reading.
- Check the stock is stored by product, with the expiry date visible.
- Check the storage range for each product on the label, not from memory.

9. Procedure

Follow the steps in order. Where a step says "If", take the action for the case that applies. Do not skip a step. If a step cannot be done, use section 11 and section 12.

Step	Action	How to do it	Key point
1	Store stock correctly.	• Place products on the shelf they are designated for. Keep them away from the back wall and the fan. • Store the newest stock behind older stock (first expiry, first out). • Keep the fridge door closed except when taking stock out. Do not overload.	Airflow and placement keep the temperature even. The door is the most common point of warming.
2	Read the thermometer twice each working day.	• Read at the set times: morning and afternoon (EC). • Record the reading on PHM-FRM-001 with time, reading and your initials. • Reset the min-max thermometer after each reading, and record the minimum and maximum if it is used.	Two readings a day show the trend. A single reading can miss a failure that starts overnight.
3	If the reading is within range, continue normally.	• Note the reading in the log. • Take no further action.	Routine readings are as important as the response to a problem.
4	If the reading is out of range, act at once.	• Do not use any stock from the fridge until the pharmacist has decided. • Move the stock to the backup fridge if it is safe to do so, and check its temperature. • Label the stock "DO NOT USE – QUARANTINE" with the time, reading and your name. • Inform the pharmacist immediately, by phone if needed, and record the time you informed them.	The first hour matters. Do not wait for the next reading to act.
5	Investigate the fault.	• Check the power, the door seal, the thermostat setting, and whether the fridge has been opened repeatedly. • Inform the facilities manager with the fault description. • Record the cause on PHM-FRM-001 and in the incident report if stock was affected.	Knowing the cause prevents the next failure. Record it while it is still clear.
6	Decide on the quarantined stock.	• The pharmacist assesses each product against the manufacturer information and the time out of range. • The pharmacist either releases the stock in writing, or marks it for destruction. • Record the decision on PHM-FRM-001 and file the written release or destruction note.	No medicine is used after an excursion without a written decision. This is the control that protects patients.
7	Review the log each week.	• The pharmacist reviews the week's log, checks every day has two readings, checks any excursion has a decision, and signs. • Report any missing readings to the ward head.	A signed weekly review is the proof that the daily readings are being checked.

Decision points

- If a reading is within the storage range, record it and continue.
- If a reading is out of range, quarantine the stock and inform the pharmacist at once.
- If the fridge has failed and no backup is available, the pharmacist arranges for the stock to be moved to a safe place within the range and tells the facilities manager.

10. Special situations

Situation	What to do
Vaccines	Follow the vaccine cold chain plan. Any excursion is reported to the immunisation lead and the pharmacist before any dose is given (EC).
Emergency kits and transport boxes	Check at the start of each shift or journey. Record in the same log (EC).
Power failure	Use the backup plan. Keep the doors shut. Read the temperature every hour until power returns (EC).
Stock delivered	Check the delivery temperature on arrival. Store at once. Record any delivery outside range.

11. Problems and escalation

- Any excursion goes to the pharmacist at once, and is reported through INC-POL-001 if stock was affected.
- If the pharmacist cannot be reached within one hour, the clinical director decides on quarantined stock.

12. Monitoring and compliance

What is checked	Target	How often	Who	If the target is missed
Days with two temperature readings recorded in the last 3 months	100%	Monthly audit of the log	Pharmacist in charge	Re-training; ward review
Excursions with a documented pharmacist decision within the same shift	100%	Monthly	Pharmacist in charge	Escalated to clinical director
Weekly review signed	100%	Monthly	Pharmacist in charge	Re-training; escalation

13. Records

Record	Where it is kept	Kept for
PHM-FRM-001 Fridge Temperature Log	Ward or pharmacy file	3 months minimum on site, then archived for {{facility.records_retention_years}} years
Quarantine and release or destruction notes	Pharmacy file	{{facility.records_retention_years}} years
Incident report (INC-POL-001)	Incident log	{{facility.records_retention_years}} years

14. Training and competence

- All staff who store or use medicines are trained in this SOP at induction and each year (EC).
- Staff are assessed by observation of the daily reading and the excursion response.

15. Related documents

ID	Title	Relationship
PHM-FRM-001	Fridge Temperature Log	Used in steps 2 to 6
PHM-FRM-002	Controlled Medicines Register	Controlled medicines are recorded separately
SOP-044	Medicine and Product Check Procedure (generic)	Used before supplying medicines
SOP-058	Product and Medicine Recall Procedure (generic)	Used if a batch is affected by an excursion

16. Evidence

ID	Source and status
E-009	ASF Expert Committee consensus. Storage ranges come from product labels. Reading times, calibration interval and backup plan are EC decisions to confirm against WHO or national cold chain guidance before approval.

EC = ASF Expert Committee consensus. Items marked EC are reviewed by the Committee each year.

17. Change history

Version	Date	What changed	Approver and signature
1.0	{{document.effective_date}}	Full procedure written; added storage rules, excursion response, pharmacist decision, weekly review and vaccine notes	Approved by the ASF Expert Committee