



PHARMACY REFRIGERATION MAINTENANCE

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Maintenance & Calibration Checks for Pharmacy Refrigerators

This is a cumulative guide based on information collated from legislative agencies

Why have calibration and maintenance checks?

To meet Cold Chain Compliance. Good Distribution Practice (GDP) states: *“Equipment, repair, maintenance, and calibration operations should be carried out in such a way that the integrity of the medicinal products is not compromised”*.

In order to achieve this - legislative agencies such as. MHRA, RPS, and GDP recommends annual maintenance and calibration checks to ensure that pharmacy refrigerators are operating correctly.

Between annual checks general maintenance is also required such as regular cleaning and defrosting. This guideline can be found in the **Standard Operating Procedure Manual (SOP)** which is designed to ensure correct maintenance of the cold supply chain of pharmaceuticals. The SOP States that a fridge should be cleaned and, if not automatic, defrosted on a regular basis (monthly).

It can be easily assumed that your pharmacy refrigerator is operating efficiently but a lot of things can affect it's optimal performance. Potential maintenance issues include:

- Over-packing which may result in the blocking of the fan which circulates the air and lead to the pharmacy refrigerator freezing up. Products should be stored in an orderly fashion on shelves not on the floor of the unit — to ensure air circulation and consistent temperatures throughout. **Ref: Steve Todd. GDP Medicines Inspector, MHRA.**
- The door left open for a long period of time.
- An accumulation of dust and dirt around the compressor and condensor during standard operation which can affect operation of the cooling system.
- Elevated environmental temperatures where the pharmacy refrigerator is situated. (To meet the demands of high temperature climates - some pharmacy refrigerators have a higher tolerance for high ambient temperature and superior CFC-Free Insulation, N/A to the UK).
- Another potential hazard that may be overlooked is: ordering an appliance that is too much of a tight fit for the space it's going into. Pharmacy refrigerators require sufficient space for air circulation and ventilation to avoid a rise in temperature surrounding the appliance.

Regular maintenance will increase the life span, reliability, and energy efficiency of your system. More importantly - Cold chain compliance is paramount to patient safety. Also essential for medicine recall wastage.

Temperature Monitoring

Attentive monitoring of your pharmacy refrigerator will soon flag up any fluctuation in temperatures and potential hazards that could affect operation. If your pharmacy refrigerator is fitted with an audible or visual alarm, don't assume that it is working unless it has been routinely tested to confirm correct operation.

Specification required for a Pharmacy Refrigerator

- 1. Temperature between +2°C and +8°C:** Temperature monitoring is recorded by a calibrated electronic min/max thermometer, with an accuracy of $\pm 0.5^\circ\text{C}$, which can be read without opening the refrigerator door.
- 2. Fan assisted:** The air within this type of refrigerator is circulated by a fan, which provides a uniform temperature profile and a rapid temperature pull down after the door has been opened.
- 3. Lockable:** Additional benefits are that pharmacy refrigerators can be locked.
- 4. Audible and visual/high and low alarm:** These alert & alarm systems alert staff in the event of temperature deviations, for example: if the door is left open, giving you ample time to restore the inside of the fridge to the correct temperature without loss of products or endangering health.
- 5. Maximum and minimum recording:** The temperature should be checked a minimum of once a day using a minimum and maximum thermometer in accordance with the manufacturer's instructions. FOR VACCINE STORAGE: (Each fridge will have its own internal thermometer). This is then checked with the digital fridge display. A loss of power will result in the loss of temperature display, hence the need for the internal thermometer as well. **The Green Book, chapter 3' states:** *"At least one maximum-minimum thermometer that is independent of mains power should be used (as well as any integrated thermometer), so temperatures can be measured in the event of electricity loss."*

Other features to consider:

Data Loggers: Temperature monitoring systems can record temperatures at configurable intervals (e.g. 30 or 60 minutes) to ensure that pharmaceuticals are stored at the correct temperature and that the pharmacy refrigerator is working properly. This feature is a bonus for maintaining regulatory compliance as it provides a complete audit, and especially useful when clinics are closed or members of staff are unavailable to check and record refrigerator temperatures consistently.

A data logger can indicate the actual length of time a pharmacy refrigerator was out of range whereas a thermometer will only display whether it was out of range according to the parameters set. Considering the expense of high value medications the use of data-loggers could potentially serve as assurance against financial loss and mechanical failure.

Even though certain medications can exceed the labelled storage temperature requirements for brief periods without a data logger; the length of time the pharmacy refrigerator has been out of range cannot be verified and therefore products more likely to be destroyed to be destroyed.

Should I purchase a Glass or Solid Door model? Many refrigerators have glass fronted doors giving greater visibility to stock levels, aiding stock management and also deterring the storage of non-medicinal products. A solid door pharmacy refrigerator will be a better option if it is to be located in direct sunlight or in a public area where the contents should be hidden.

Action - to be taken in the event of temperature deviations:

Temperature records should identify any temperature deviations and give details of corrective actions taken as a result. For instances - where there has been a temperature deviation, best practice would be to take a further reading later the same day to ensure that it was a transient deviation and show that the temperature was now back within prescribed parameters. **(Royal Pharmaceutical Society RPS)**.

QED Scientific© Maintenance and Health Checks

On a maintenance visit QED Scientific check the following:

- Internal condition of chamber, shelves, shelf supports
 - Internal fan is working, check for signs of fan excessive wear or possible failure
 - External condition
 - Door hinges and door seals - Integrity of glass doors
 - Feet, stability of cabinet
 - Temperature controls within prescribed limits +2C to +8C
 - Calibration check traceable to UKAS (we use approximate geometric mid-point)
 - Alarm check
 - Clean condenser and compressor area
 - Clean defrost drain
- + Issue a written report with UKAS traceable certificate.**