



Monitoring Methods & Troubleshooting

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Monitoring Methods

- The Options
- Thermometers
- Min/Max Thermometers
- Chart Recorders
- Data Loggers
- Centralised/Computer Systems

The Options



- Several monitoring methods available
- Difference between methods are:
 - Accuracy
 - Amount of data – sampling interval
 - Data currency – sampling period
 - Cost
 - User input
 - Calibration
 - Sampling point – air, containers etc.

Thermometers



Advantages

- Inexpensive
- Accurate
- Can be used within containers
- Easily re-calibrated

Disadvantages

- Only record current temperature
- Potential for false highs
- Open to observational error
- Requires operator to perform measurement
- Easily broken – mercury spillage

Min/Max Thermometer

- There are now two types of these available
- Old style ones containing either mercury or spirit
- New style electronic ones
- Pros and cons with each
 - Old style can be fragile
 - New ones can run out of battery!
- Minimum requirement for Pharmacist Code of Ethics / Orange Guide (electronic)



Min/Max Thermometers



Advantages

- Inexpensive
- Shows current temp as well as min/max over a period
- Electronic ones can have in-load probes

- Disadvantages
- False highs (if removed from fridge)
- Breaks in mercury channel can give false readings
- Need to reset each time they are read
- External calibration

Chart Recorders



- Chart recorders consist of a chart on to which a pen scribes.
- The pen is attached to a temperature indicating bimetallic strip and a quartz clock movement rotates the chart.
- The chart paper is circular and has time/day printed around the circumference and temperature across the radius.

Chart Recorders



Advantages

- Creates synchronous raw data over a time period
- Results easily archived and copied
- Real time and retrospective data
- Around £100 to £250

Disadvantages

- Can be knocked or easily damaged giving false results
- Relatively slow response time
- Charts, pens and batteries require regular changing
- Splash proof not waterproof
- Narrow temperature range
- May or may not have external probe

Data Loggers



- These consist of one or two temperature sensors, which are connected to a microprocessor, which stores the data samples in a memory chip.
- They are capable of storing several thousand samples
- The data is normally downloaded to a PC where the data can be viewed and archived
- Available with a built in LCD display, which shows current temperature, minimum, and maximum temperature
- Can have internal or external sensors

Data Loggers



Advantages

- Can measure data over a long period
- Can have external probes
- Portability – e.g. cold chains
- Wide temperature range

Disadvantages

- Data is retrospective
- Requires user input to download
- Requires PC and dedicated software to download

Centralised/Computer Systems

- These systems normally involve sensors either being hard wired or linked via radio frequency to a central computer system.
- The software associated with these systems allows the user to view real time and logged temperature in multiple locations.
- They may also be configured to alarm if a sensor reading differs from preset parameters and raise alarms which may include contact the out hours service.

Centralised/Computer Systems

Advantages

- Real time and retrospective data
- Configurable alarms
- Different sensors can be attached
- Low user input required
- External access e.g. by on call staff

Disadvantages

- Higher initial outlay
- May require some hard wiring
- Some systems may require dedicated PC/software



Monitoring Methods Summary

- Choice is dependant on several factors
 - Initial cost/outlay
 - Accuracy
 - User Input
- Don't underestimate the amount of user input required including training
- What about the chance of human error?
- It is always a balance between cost and the amount of robust data required

Troubleshooting



- This section we will go through a list of common problems encountered in the temperature control and monitoring of storage areas. It is divided into sections for types of storage areas
 - Refrigerators and freezers
 - General storage areas

Refrigerators & Freezers – Out of Specification Results

- *Has the unit door been opened during monitoring for a prolonged period?*
 - Opening the door of the unit will cause false high readings. It is important that the door is not opened for prolonged periods.
- *Has there been an interruption in power to the unit?*
 - If there has been an interruption in the power supply to the unit this may result in the unit resetting itself and the settings being altered.
- *If the readings were high was it a result of a false high reading during recording?*
 - If using a min/max thermometer it is possible to obtain a false high reading if the probe/unit is removed from the cabinet and not read promptly. Where possible use a digital device with which the probe is not removed from the cabinet during recording.

Refrigerators & Freezers – Out of Specification Results

- *Have the settings been altered?*
 - The settings may have been altered during monitoring – this can be as a result of an interruption in power, user intervention or the control module being knocked.
- *Location – has there been any significant variation in environmental temperature surrounding the unit?*
 - Significant changes in temperature, especially heat, can put undue stress on the unit causing performance to deteriorate. Units should be sited in a stable environment
- *Does the cabinet require defrosting?*
 - Check for significant ice build up in the cabinet as this can adversely affect the units performance

Refrigerators & Freezers – Out of Specification Results

- *Has the cabinet been knocked or damaged?*
 - Check the unit for visible signs of damage as this can have an adverse effect on performance.
- *Have the recording devices been calibrated or checked against a calibrated device?*
 - Any recording devices used must have either a valid calibration certificate or have been checked against a calibrated unit. Uncalibrated devices may produce false results and any data produced is invalid.
- *Has the stock temperature equilibrated?*
 - If the stock temperature has not equilibrated then this can cause out of specification results to be obtained.

Refrigerators & Freezers – Out of Specification Results

- *Are the door seals functioning correctly?*
 - If the door seals are damaged then poor unit performance may result. A simple check for the door seals is to open the unit door, close it immediately and then try to open it again. On re-opening you should feel a resistance created by the contraction of air, this is more noticeable with fan assisted refrigerators and freezers. If the door opens easily then this may indicate faulty door seals.

Refrigerators & Freezers – Damaged door seal



Ice build up
due a poorly
functioning
door seal

Refrigerators & Freezers – Out of Specification Results

- *How has the stock been packed?*
 - If the stock has been incorrectly packed and there is insufficient airflow around it this will result in poor performance and may cause out of specification results. Out of specification results may be produced if there is too much stock in the unit so try reducing the amount of stock. If this remedies the problem then this will affect the amount of stock that may be stored in the unit when it is in service.

Loading Patterns

Solid containers decrease airflow



Cramped, poorly loaded stock decreases airflow

Mesh containers allow good airflow around stock



Stock spaced to allow airflow around containers

Refrigerators & Freezers – Out of Specification Results

- *Have stock levels significantly changed in the cabinet?*
 - If stock has been placed in the unit then the door will have been opened and a false high recorded also this extra stock will take time to equilibrate again, with the potential of causing a high result.
- *Is there a gap between the stock and the chiller plates/fans?*
 - In most domestic type refrigerators the chiller plates are located at the rear of the cabinet and it is important that there is at least a 5cm (2 inches) between the stock and the rear of the cabinet. It is also good practice to leave this size of gap at the top, bottom and sides of the unit to allow good airflow. If the fan is blocked by stock being too close in a fan assisted unit this will have a detrimental effect on airflow within the cabinet and may cause out of specification results.

Sensor Positioning

- *Where is the sensor for the recording device located?*
 - If the sensor for the recording device is located next to the chiller plates or in the direct flow from the refrigeration unit this will give lower results whereas if the sensor is in an area of restricted air flow then high results will be obtained. Units should be temperature mapped so that hot and cold spots identified and best position for routine monitoring sensors located. The map should also indicate where types of stock should be located in a unit i.e. vaccines should be away from areas where they could freeze.

Poor Sensor Positioning

Sensor blocked by shelving – restricted airflow



Sensors in close proximity to door – potential for false high readings



Sensors beneath chiller unit – not indicative of overall temperature

General Storage Areas

Out of Specification Results

- *Have the environmental conditions changed?*
 - During summer and warm periods the temperature in uncontrolled areas can rise significantly. Also heating systems may be turned up in winter creating excessively warm conditions. The criteria for room temperature storage is 15 to 25°C and although brief excursions up to 30°C may be tolerated storage at any temperature above is unacceptable and most pharmaceutical manufacturers will not guarantee stock exposed to these conditions.

General Storage Areas

Out of Specification Results

- *Are heating or air conditioning systems operating correctly?*
 - If heating or air condition systems malfunction this can cause changes in temperature. Also they should be checked for whether they switch on and off at certain times. If this happens this may result in significant and potentially damaging temperature cycling. These systems should be optimized so as to give an even temperature throughout the day and not just in working hours.
- *Has the sensor been insulated by stock?*
 - If stock is placed directly in front of the sensor then this will insulate it and cause false reading to be obtained. It is important that all staff know about the sensors and that stock should not be placed directly in front of them.

Recommendations

- The use of dedicated refrigerators is recommended.
- Units should have fan assisted cooling
- Units should have digital temperature control.
- The use of domestic refrigerators for the storage of pharmaceuticals is not recommended as they have poor temperature control and are not fan assisted

Recommendations

- The use of cold rooms instead of a bank of several stand-alone refrigerators is recommended.
- When purchasing a cold room it is important to specify that it should have twin chiller units and an external alarm in case of breakdown.
- Users should also have a plan as to relocation of the stock in the event of a breakdown

Recommendations

- Monitoring method
 - Smaller units – data loggers or chart recorders
 - Larger units – centralised computer systems
 - Cold chains – data loggers

What can go wrong!

NEVER FROZEN	FROZEN/ THAWED
IMMEDIATELY AFTER SHAKING	
Smooth and cloudy → 	← Not smooth, granular particles 
30 MINUTES AFTER SHAKING	
Starting to clear →  No sediment →	← Almost clear  ← Thick sediment
USE VACCINE	DO NOT USE VACCINE

Any questions?

