*Abstract*

*The lag time between a sample of approx 400ml and air @ 8 °C has been established at in excess of 60 minutes. If monitoring systems are set to alarm on product temperature a considerable window of opportunity to take corrective action has been missed.*

# Temperature Monitoring Systems…….Monitor Air or Monitor Product?

Introduction.

The use of a temperature controlled unit (TCU) to store or incubate material, is often supported by the use of independent temperature monitoring systems. Many facilities operate a system of continuous temperature monitoring. The rational is often to allow reaction time to any deviations allowing the product to be relocated before any adverse impact will have been created.

Most systems allow for dynamic operation, opening up fridges and freezers consequentially leads to a rise in temperature. The temperature increase may be of long or short duration, dependant on many factors such as ambient air temperature, duration of door opening, how wide the door was opened, temperature of materials added, ability of unit to recover…….

How best to integrate a monitoring system and minimise "false positive" alarms is an issue faced by many. Simple laws on thermal dynamics suggest mass of thermal point being measured will be significant on the time of response obtained. However on researching this facet there appeared to be little published data to support the fact. At C&M Scientific we undertook a simple experiment in order to establish some core data that might prove the time / temperature influence of sample size.

Method:

A range of typical laboratory samples were stored in a standard refrigerator. All samples were allowed to stabilise to a temperature ≅ 4 °C. Once all samples and the chamber air were equilibrated, the power to the fridge was switched off. Through the exercise the temperature was being logged. The aim was to establish the time differential when each sample exceeded the temperature threshold.

Materials:

The samples used were as follows:

2 ml plastic cryovials (1.8ml of water)
15 ml plastic falcon tube (10 ml of water)
50 ml plastic falcon tube (45ml of water)
175 T Flask (200 ml of water)
Blood bag (400 ml of water)


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Equipment
5.8 cuft refrigerator.
Datalogger with type T thermocouples (Grade A)

Results:

| Time /oC | Chamber Air | Cryovials | 15ml Tube | 50 ml tube | Cell flask 200ml | Blood bag 400ml |
|---|---|---|---|---|---|---|
| 6 °C | 14:39 | 14:42 | 14:53 | 15:10 | 15:36 | 15:29 |
| 8 °C | 15:02 | 15:07 | 15:20 | 15:38 | 16:07 | 16:13 |
| 10 °C | 15:36 | 15:37 | 15:56 | 16:10 | 16:43 | 16:58 |

The time/temperature points were selected on the basis of C&M Scientific's client base experience.
The data shows that the sample sizes significantly influences the time/temperature relationship the following table shows the time differential in minutes between the "Chamber Air" temperature and the time taken for each of the test samples to attain the corresponding temperature.

Time differential in "minutes" base point Chamber Air temperature.

| Chamber Air | Cryovials | 15ml Tube | 50 ml tube | Cell flask 200ml | Blood bag 400ml |
|---|---|---|---|---|---|
| 6 °C | +3 | +14 | +31 | +57 | +50 |
| 8 °C | +5 | +18 | +36 | +65 | +71 |
| 10 °C | +1 | +20 | +34 | +67 | +82 |

Discussion:

Masking the monitoring system probe by immersion in a sample material or increasing the thermal mass of the sensor is commonplace. This strategy is normally employed to assure that false positives due to dynamic operations are avoided. While empathising with the concept, it would be essential to establish the time/temperature relationship of the weighted probe to the sample types and volumes being stored.
The exercise we conducted showed that the time differential between air temperature and product temperature going out of range could be in excess of 1 hour. This means that if the response to air temperature is utilised there is a significant increase in the time window of action prior to samples being influenced by temperature. If the weighted senor concept is used the window of opportunity to respond will be considerably reduced.


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It is accepted that immediate response to air temperature would result in alarms due to normal dynamic operations (false positives). When introducing systems for the first time this can give rise to a "cry wolf" syndrome and serious alarms are ignored. Experience has shown that using a combination of Chamber Air and a lag time offers the most assured method of minimising out of specification sample material.

The experiment we under took only considered sample volume and the containers were chiefly constructed of similar lightweight plastics. Glass bottles, cardboard packages, foil packages, fluids, solids, powders etc. all have different responses to temperature over time.

By recording data profiles over time, concerns of time temperature impact may be reviewed by the application of the Mean Kinetic Temperature (MKT). Many monitoring system vendors now support such calculations within their software packages. The use of MKT is finding acceptance in many industries, as it presents a mathematical model which supports the continued use of product or materials despite data from monitoring systems showing temperature excursions during storage.

**Conclusion:**

Where homogeneous product is to be stored in a TCU, it is feasible to establish the temperature / time relationship for a product. Allied to thermal mapping it is therefore possible to establish how and where to place monitoring system probe(s).
Where non homogenous product is stored we would suggest monitoring chamber air only. Should false positives present then the judicious use of alarm delay should be applied.

For further discussion and details of the testing conducted contact:

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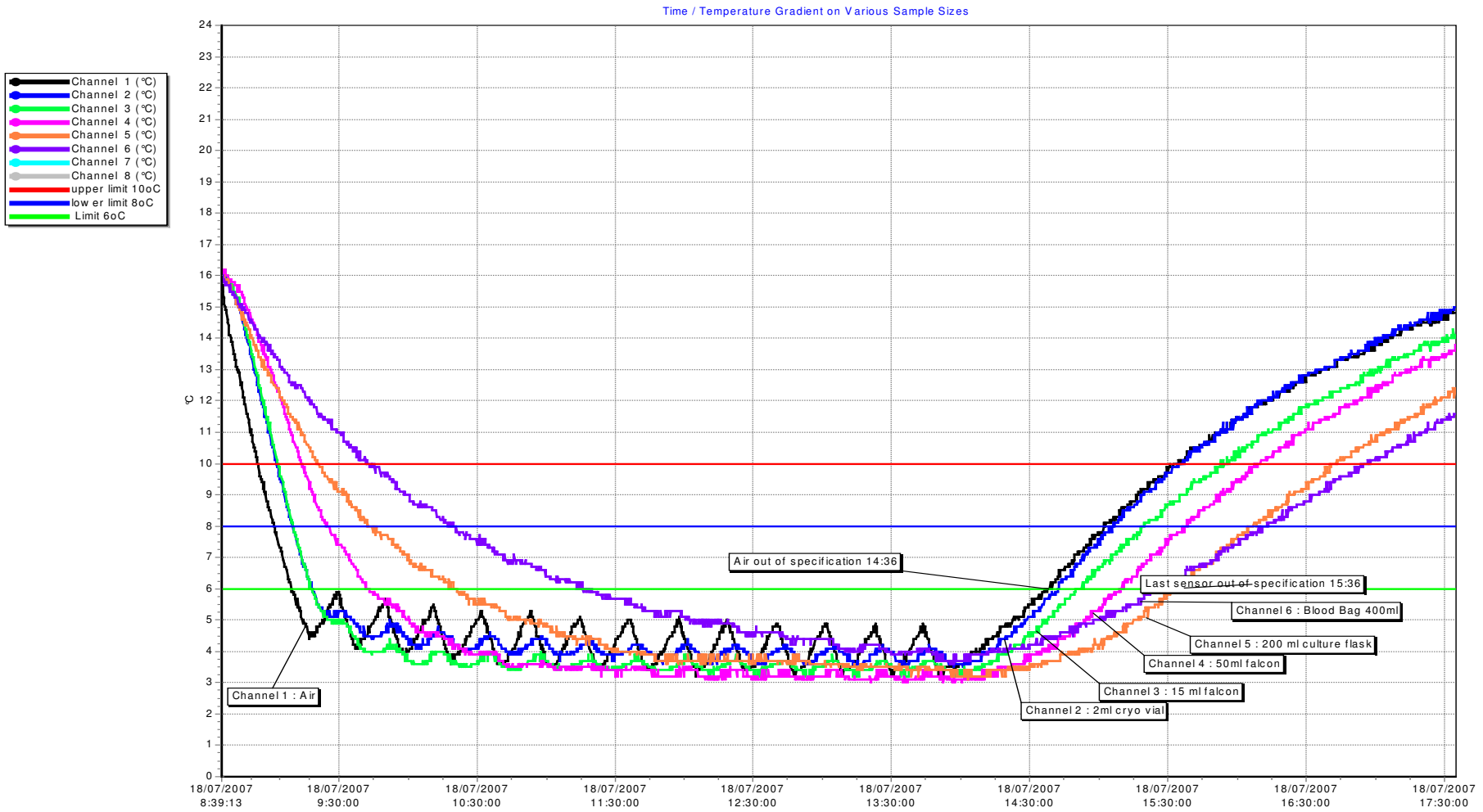




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