

Temperature measurement inside a FRIO-Wallet

by D G Spendley PhD CPhys MInstP MIPEM

British Medical Devices Evaluation Unit

Introduction

The FRIO-Wallet is intended to keep its contents cool for extended periods. The measurements discussed in this report were undertaken to investigate the temperature response for small amounts of water held in sample vials over periods of hours when stored in a FRIO-Wallet used in high environmental air temperatures. The effect of different humidity levels on the performance of the wallet was also investigated.

To examine the response of the small sample to exposure to the environment a measurement was also made of the temperature of a water sample when suspended freely in the incubator.

Method

The temperature measurements were made in an Air-Shields Isolette C550 XL infant nursing incubator. This incubator is intended to provide a closely controlled micro-climate for very small and sick infants and can maintain a very stable air temperature close to 37.8° (100°F) with very little variation. The relative humidity inside the incubator was controlled for these measurements by using the Air-Shields Dewette 2 Servocontrolled humidity system.

Two plastic sample vials used for storing blood samples each had a hole drilled in their cap to accommodate a platinum resistance thermometer. The vials were filled with 5ml of water and were cooled in the refrigerator to approximately 5°C before being placed in a FRIO-Wallet that had been activated by total immersion in cold water for 90 seconds.

The activated FRIO-Wallet was then suspended vertically in the centre of the incubator so that all surfaces were exposed to the air. The sample vials were then placed in the wallet. Two platinum resistance thermometers were mounted horizontally in the incubator outside the wallet, one near the bottom of the wallet and one near the top to measure the incubator air temperature.

The relative humidity was controlled at different values for the measurement periods. Temperature and relative humidity data were logged automatically at intervals for the duration of the tests which was up to 48 hours.

Equipment

The temperatures were measured using platinum resistance thermometers of length 100mm coupled with a Fluke Hydra 2650 Data Acquisition Unit. The thermometers had been previously calibrated in a water bath by comparison with a Rosemount 162N Platinum resistance thermometer and Fluke 8520 Bridge. The uncertainty of calibration of the platinum resistance thermometers was $\pm 0.05^{\circ}\text{C}$ with a confidence probability of not less than 95%.

The relative humidity within the incubator was measured using a Vaisala HM1132 relative humidity meter with an uncertainty of measurement of $\pm 1\%$ RH or a B&K Climate Analyser 1213 with an uncertainty of measurement of $\pm 1\%$ RH.

Results

Data was logged for 48 hours and the resultant plot of temperature against time is shown in Figure 1.

Sensors 1 and 2 were in the sample vials in the FRIO-Wallet, sensor 6 and sensor 10 were mounted in the incubator air. The average incubator air temperature was 38.1°C. Both the sample temperatures remained below 26.5°C for the duration of the measurement period. See graph Figure 1.

The foregoing details are extracts from Dr Spendley's reports carried out between March 1996 and September 1997.

FRIO® Wallets were submitted to the FDA in the US in 1997. Following their examination they have been approved for sale throughout the USA.

Frio-Wallet Temperatures

