WHITE PAPER

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Temperature Intelligence®

Validation of Blood Temperature Indicators

Comparison of Three Temperature Probe Placements

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A study was performed to highlight the differences observed during Safe-T-Vue® indicator validation when using three different temperature probe placement positions to measure the temperature of simulated blood bags.

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Results show that the way in which the temperature is measured (e.g. probe location) affects the temperature output as bags removed from the same refrigerated storage conditions warm at room temperature conditions.

Results highlight the need to select the appropriate temperature probe placement when performing the validation procedure so that the core blood bag temperature correlates to the actual temperature indicator performance. This will also avoid unnecessary wastage of "good" blood products that may appear to be out of AABB guidelines but are within guideline limits when properly measured.

Test Group 1

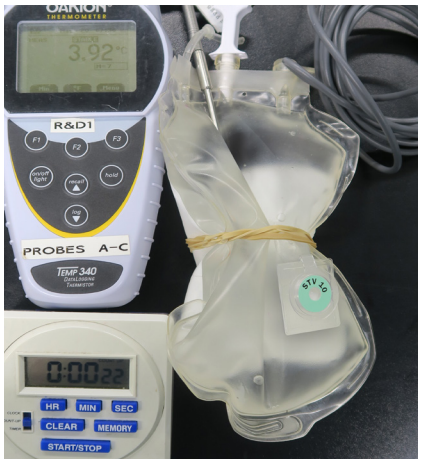
Internal, Core Temperature:

Probe into Center of Fluid-Filled Bag

Test Group 2

External, Surface Temperature:

Probe Taped to Surface of Fluid-Filled Bag



Test Group 3

External, Surface Temperature:

Fluid-Filled Bag Wrapped Around Probe

Experimental Details

PVC blood bags from Charter Medical were filled to contain 350mL of a mixture of 10% glycerol and 90% water to simulate red blood cell volume. Each bag was pre-conditioned for at least 24 hours inside a controlled temperature refrigerator (1ºC to 4ºC) prior to performing the test. Calibrated temperature-sensing probes were used along with calibrated Oakton Thermistor Thermometers (having a measurement accuracy of at least ±0.1°C) to measure temperature as follows:

Test Group 1: temperature probe inserted into the center of the fluid-filled blood bag, measuring internal core temperature

Test Group 2: probe taped securely to the external surface of the fluid-filled blood bag, measuring surface temperature

Test Group 3: fluid-filled bags positioned to wrap around the probe, measuring external, core temperature

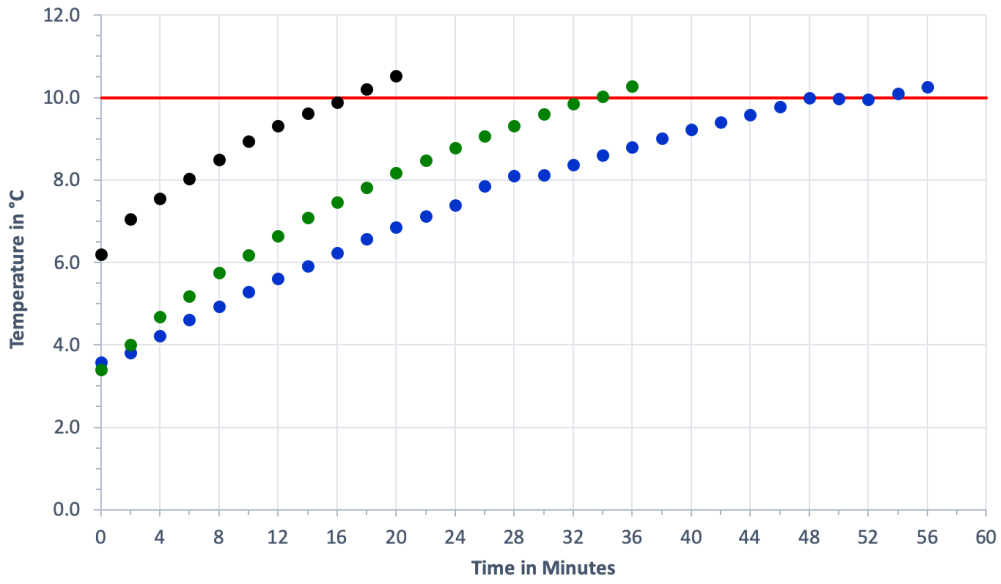
Note: Although the temperature measurement probes in Test Group 3 are positioned on the surface of the fluid-filled bag, wrapping the bag around the probe changes the geometry of the bag, which in turn affects heat transfer. This set-up becomes an “artificial” core temperature that no longer accurately represents the temperature of the actual fluid contents.

After pre-conditioning for at least 24 hours, the bags were removed from a Darwin refrigerated incubator (maintained between 1°C to 4°C) and placed lying flat on a counter-top at room temperature conditions (17.5°C with 32% R.H). A timer was set to count-up mode and temperature readings were recorded at one minute intervals until the temperature reached 10°C.

Results

The time and temperature data was collected for each of the bags in the three different test groups. At least six (6) bags were tested for each bag/probe location. The graph below shows the average time required for pre-conditioned bags to warm to 10.0°C when removed from refrigerated conditions and placed on a counter-top at room temperature.

Simulated RBC Fluid-Filled Bag, Time to Reach 10°C. Surface temperature vs Internal Core Temperature Measurement.



Test Group 1:
Internal Probe Measurement,
Inserted into Center of Fluid-Filled Bag

Test Group 2:
Surface Probe Measurement,
Taped to External Surface of Fluid-Filled Bag

Test Group 3:
Surface Probe Measurement
Fluid-Filled Bag Wrapped Around Probe

Each data series plotted on the graph represents the average times for six (6) fluid-filled bags to warm to 10°C under typical room temperature conditions upon removal from refrigerated storage (1°C to 4°C). The graph plots the mean temperature measurement of each test group at 2-minute increments.

- Test Groups 1 and 3 show start temperatures within range of the storage refrigerator (1°C to 4°C).
- Test Group 2 with probes adhered directly onto the surface of the bag show higher start temperatures (e.g., around 6°C) immediately upon removal from the same refrigerated storage conditions when compared to the other Test Groups.
    - Although the measurement probe is adhered directly on to the bag surface, a temperature offset likely arises as a result of the probe being exposed to warmer air in the surrounding test environment.
- Test Group 3 have similar starting temperatures upon removal from refrigerated storage (approximately 3.5°C). However, wrapping the bag around the probe changes the configuration of the bag and heat transfer of the fluid inside, as reflected by the slower rate of temperature change over time. This artificial "core"

temperature measurement proves to be an ineffective method of measuring actual core temperature as the geometry of the bag is altered and manipulated by the user.

- Test Group 2 and Test Group 3 are methods that do not correlate to the function, design, and performance of the STV indicator. Using these methods could lead to an incorrect validation result.

Conclusions

Surface temperature methods will not provide an accurate indication of internal core temperature. Results confirm that the suitable method for measuring the actual temperature of the fluid inside the bag is by inserting the temperature probe directly into the center of the fluid-filled bag.

While Safe-T-Vue indicators are intended for application directly onto the surface of a blood unit, the indicator color response is formulated and designed to correlate to internal "core" temperature. Therefore, when performing validation of Safe-T-Vue indicators, or any other blood temperature indicator, it is important that core temperature measurements are obtained on fluid inside bags that are kept intact. Otherwise, results from a surface or artificial "core" temperature measurement validation may lead to valuable blood product being disposed of unnecessarily.

It should be noted that the surface temperature measurement conditions in this study were recommended as real-life scenarios observed in the field by Safe-T-Vue users performing validations. The recommended procedure for validation appropriately measuring the internal core temperature is described in Control Doc #2065 COMZ Suggested Validation Procedure for Safe-T-Vue 10 and Doc# 2064 COMZ Suggested Validation Procedure for Safe-T-Vue 6.