



# Blood Temp Indicator +10°C/50°F: Testing Protocol

Inert Prior to Arming/Activation



Armed Activate



Breached Core Temperature 10°C



## Purpose:

To validate the Blood Temp Indicator when used as a temperature indicator attached to blood bags manufactured from flexible plastic. The indication window will progressively change color from white to blue when the core temperature of the blood in the bag reaches the compliance upper limite of 10°C.

## Equipment:

1. A refrigerator with temperature controlled between 1 °C and 8°C.
2. A blood bag having filled to capacity ( =350cc) with blood or glycerol water mixture to simulate blood.
3. A calibrated thermometer or temperature probe with an accuracy of  $\pm 0.5^{\circ}\text{C}$

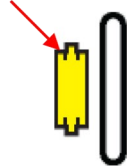
## Method:

1. The thermometer or probe into the pre-filled blood bag.  
The thermometer or probe tip should be positioned in the center of the blood bag liquid mass to measure the core temperature of the blood (approximately at the blood bag bottom 1/3)
2. Store blood-bag (with the inserted thermometer) in the refrigerator for at least 24 hours prior to testing to ensure blood is at correct storage temperature.  
Note that the Blood Temp Indicator should not be preconditioned nor attached to the blood bag.
3. Remove blood bag (with the inserted thermometer) from the controlled refrigerator to ambient after 24 hours.
4. Activate the Blood Temp indicator by a firm squeeze on the product blister between two finger tips. Verify that the activation window changes color from yellow to dark green.

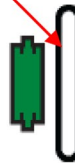
Product Blister



Activation Window



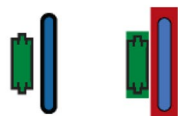
Indication Window



5. Remove the Blood Temp indicator from the adhesive liner and attach it directly to the blood bag at the approximate center of blood mass directly above the thermometer or probe end at the bottom 1/3 of the blood bag.
6. Optional: Replace blood bag with the attached indicator (and the inserted thermometer) back to the controlled refrigerate for as long as required. Verify that the indication window has not changed color (i.e. still white).

This confirms that the indicator has stopped and the colorant is in a solid form. Remove bag with the attached indicator (and the inserted thermometer) to ambient.

7. Validate that the indication window has progressively changed color from white to blue when the core temperature breaches 10°C



8. Repeat process with one or more Blood Temp indicators as required.