

Inactive prior to arming



Armed with no temperature breach



Armed and temperature breach has occurred.



Purpose:

To validate the ShockWatch Blood Temp 10 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 upper limit of 10°C.

Equipment:

1. A refrigerator with temperature controlled between 2°C and 6°C.
2. A blood bag 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. Insert 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. Verify that the blood bag core temperature has stabilized to reach relevant blood bank regulation temperatures.

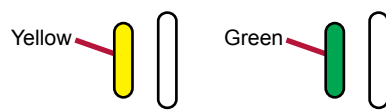
*Note that the Blood Temp 10 indicator should NOT be preconditioned nor attached to the blood bag.

3. Remove blood bag (with the inserted thermometer) from the controlled refrigerator to ambient.
4. Arm the Blood Temp 10 indicator by firmly squeezing on the product blister between two finger tips. Verify that the arming window changes color from yellow to green.

Product Blister



Arming Window



5. Remove the Blood Temp 10 indicator from the adhesive liner and attach it directly to the blood bag at the approximate center of blood mass (the bottom 1/3 of the blood bag) directly above the thermometer or probe end.
6. Optional: Replace blood bag with the attached indicator (and the inserted thermometer) back into the controlled refrigerator for as long as required.

Verify that the breach window has not changed color (i.e. still white). This confirms that the indicator has stopped and the colorant is in a solid form.

7. Remove bag with the attached indicator (and the inserted thermometer) to ambient.
8. Follow the measured temperature via the thermometer and verify that the breach window has changed color from white to blue soon after the measured temperature has breached above 10°C

Breach Window



9. Repeat process with one or more Blood Temp 10 indicators as required.