



Manufactured by:
Temptime Corporation
116 The American Road
Morris Plains, NJ 07950

Guideline Protocol

For

Activation Choices for:

**Safe-T-Vue® 10
and Safe-T-Vue® 6**

1. Purpose:
To provide choices and guidance about *Activation* of Safe-T-Vue Products, where Activation is the term used to describe the removal of the lid material on a Safe-T-Vue Product, exposing the red and white disks, and pressing the white disk into the red disk.
2. Scope:
This procedure applies specifically to Safe-T-Vue 10 and Safe-T-Vue 6 temperature indicators.
3. Reference:
 - 3.1. *Safe-T-Vue* Product Sheet.
 - 3.2. *American Association of Blood Banks Standards for Blood Banks and Transfusion Services*, Current Issue, Reissue of Blood and Components.
 - 3.3. Package insert "*Instructions & FAQs*".
4. Responsibilities:
 - 4.1. Training to assure consistent handling and application of Safe-T-Vue Products.
5. Safety:
N/A
6. Attachments:
N/A
7. Materials / Equipment:
 - 7.1. Safe-T-Vue® 10 and Safe-T-Vue® 6.
 - 7.2. Optional Cold Pack, 18 to 24 ounce for a 350 cc bag.
 - 7.3. A refrigerator with temperature controlled between 1° and 4.0° C.
 - 7.4. A simulated blood bag having 350 cc +/- capacity filled with the appropriate volume of 10% glycerol-water mixture to simulate blood mass and volume.
 - 7.5. A calibrated electronic thermometer with an immersion probe or equivalent.
 - 7.6. The thermometer (or electronic probe) is inserted into the bag and positioned so that it is in the approximate center of the glycerol-water mixture to assure temperature measurement of the 'core' temperature of the liquid mass.
8. Procedure:
 - 8.1. Activation choices:
 - 8.1.1. Immediately after adhering to blood bag.
 - 8.1.2. Any time after adhering to blood bag.

8.2. General procedure for using a Safe-T-Vue Product.

- 8.2.1. Remove one Safe-T-Vue from the product box in refrigerator taking care to handle Safe-T-Vue by the round, color-coded end; [light green for Safe-T-Vue 10 or purple for Safe-T-Vue 6.
- 8.2.2. Peel off the "Remove" label to expose the adhesive and attach Safe-T-Vue directly to the blood bag where there is the greatest volume of liquid.
- 8.2.3. Timing of Activation:
 - 8.2.3.1. Immediately after placing on blood bag, in preparation to dispense blood
 - 8.2.3.2. Any time after placing on blood bag - while maintaining/storing blood bag in the blood refrigerator to assure blood is within compliance temperatures
- 8.2.4. **Activate** by stabilizing Safe-T-Vue against bag with fingertips and peel off the top foil lid to expose the red and white rounds.
- 8.2.5. Fold the white round into the red round, then press firmly together by pressing only on the colored, round label.
- 8.2.6. Blood bag with activated Safe-T-Vue applied may be dispensed immediately, or stored in the blood refrigerator until dispensed.

8.3. Critical Process Variables:

- 8.3.1. Refrigerator temperature range.
- 8.3.2. Calibration of temperature-measuring instruments.
- 8.3.3. Handling of Safe-T-Vue Product.

8.4. Conditions to be Monitored:

- 8.4.1. Storage of Safe-T-Vue Products in refrigerator so that 'warm air wash' from normal opening and closing of the door does not warm the indicators above compliance temperature prior to use.
- 8.4.2. Training to assure consistent handling and application of Safe-T-Vue Products.