Safe-T-Vue®

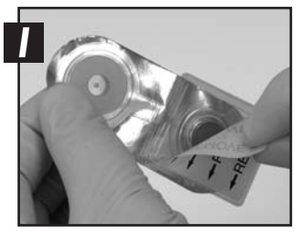
Handling/Use Instructions/Frequently Asked Questions (FAQs), and Color Change Interpretation Information

View Video Instructions at www.williamlabs.com

Application and Use

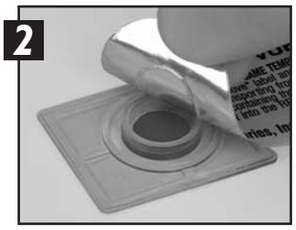
Safe-T-Vue 8 and 10 for Direct Contact Blood Bag or Temperature-Sensitive Product Monitoring

- Use of a cold pack will help maintain temperature of blood during dispensing process by placing cold pack under bag. Keep multiple cold packs in blood refrigerator to assure cold pack temperature to be same as blood bag.
- Store 50-indicator boxes of Safe-T-Vue 8 and Safe-T-Vue 10 in refrigerator with temperature below 5°C for 24 hours prior to use.
- Remove blood bag(s) or temperature-sensitive product(s) being monitored and one Safe-T-Vue 8 or 10 Temperature Indicator from the refrigerator at the same time and place blood bag on lab bench close to the refrigerator. *Take great care to handle Safe-T-Vue Indicators by the colored label end only*.

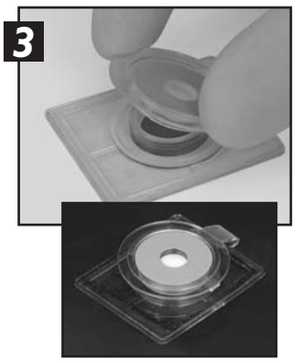


- **Follow these steps:**

Step 1: Remove the adhesive cover and place sticky end of Safe-T-Vue on the bag or temperature-sensitive product being monitored BEFORE peeling off the printed white paper/foil lid to expose the white and red rounds.



Step 2: Be certain that the Safe-T-Vue Temperature Indicator is completely in contact with the blood bag or temperature-sensitive product being monitored–no air pockets should be under the Indicator due to a fold in the bag or other obstruction. Place on area of the bag where there is the greatest volume of blood during placement and shipment or storage. Peel off the printed white paper/foil lid to expose the white and red rounds.



Step 3: To activate, firmly press the white round color-coded label end into the red round until they fully close together. Be careful to press ONLY on the white round color-coded label to activate properly.

Safe-T-Vue 6 for Direct Contact Blood Bag or Temperature-Sensitive Product Storage

- Use of a cold pack will help maintain temperature of blood during dispensing process by placing cold pack under bag. Keep multiple cold packs in blood refrigerator to assure cold pack temperature to be same as blood bag.
- Pre-apply to bag or product by removing the adhesive cover and placing sticky end of Safe-T-Vue on the bag or temperature-sensitive product being monitored. Place in refrigerator with Safe-T-Vue 6 attached for a minimum of 1 hour BEFORE activating. Be certain that the Safe-T-Vue Indicator is completely in contact with the blood bag or product being monitored–no air pockets should be under the Indicator due to a fold in the bag or other obstruction. Place on area of the bag where there is the greatest volume of blood during placement and shipment or storage.
- Since a cold start of less than 4.5°C is required, it is preferable to activate Safe-T-Vue 6 in the blood refrigerator. Alternately, Safe-T-Vue 6 can be activated IMMEDIATELY after removing the bag or temperature-sensitive product being monitored (with applied Safe-T-Vue) from the blood refrigerator.

Step 1: Peel off the printed paper/foil lid to expose the white and red rounds.

Step 2: To activate, firmly press the white round color-coded label end into the red round until they fully close together. Be careful to press ONLY on the white round color-coded label to activate properly.

Frequently Asked Questions (FAQs) About Safe-T-Vue 6, 8, and 10

Q: At what temperature should blood or the temperature-sensitive product being monitored be prior to attaching Safe-T-Vue?

A: Blood temperature should be as cold (between 2°C and 4.5°C) as possible. A low start temperature is critical to safe temperature maintenance of blood or the temperature-sensitive product during transport.

Q: How long can the blood bag or temperature-sensitive product being monitored be out of the refrigerator and avoid unnecessary warming during normal handling, labeling, and packing?

A: Based on field experience, RBCs and most temperature-sensitive products may be out of refrigeration no more than 10 minutes before issuing. If RBCs and temperature-sensitive products are out of refrigeration for more than 10 minutes they should be re-refrigerated for a minimum of 90 minutes before issuing.

Use of a cold pack will help maintain temperature of blood during dispensing process by placing cold pack under bag. Keep multiple cold packs in blood refrigerator to assure cold pack temperature to be same as blood bag.

Q: Does the temperature of the room have any effect on Safe-T-Vue?

A: Room temperature will affect heat transfer from/or to anything in it. A cooler room temperature will help keep blood bags or temperature-sensitive products cool once they are removed from the refrigerator.

Q: Cold bags often condense moisture on them after removal from the blood refrigerator. Do I need to remove it before applying a Safe-T-Vue to the bag?

A: Just before applying Safe-T-Vue, remove excess moisture by using a dry lab wipe on the surface where the Safe-T-Vue is to be applied.

Q: Do busy blood refrigerators affect blood temperature?

A: Refrigerators with high door counts should be high recovery(1) units to ensure maintenance of blood at required safe temperature. An increase of 3 to 4°C can take place in air temperature of a blood refrigerator held open for 30 seconds.

(1) Helmer brand blood refrigerators are one of several considered high recovery.

Q: Do you have any protocols for packing blood products being sent to the OR or transport to another location?

A: When packing with wet ice or reusable cold packs, follow the packing instructions provided with your *validated shipping container(2)*. The top-most layer should always be wet ice or cold packs to keep warm air from the blood bags and/or temperature-sensitive

(FAQs continued on reverse side)

products being monitored–the air above the cold packs is close to room temperature and remains that way during shipment. Avoid direct contact between wet ice packing and blood or temperature-sensitive products being monitored unless specified by your packing protocol. Use an adsorbent pad to control moisture condensation, and to act as an insulator between the blood bags or temperature-sensitive products and your wet ice or cold pack. The American Red Cross provides a packing protocol for transport of 350 mL and larger bags of WHOLE and RBCs in one of their JOB AID bulletins(3).

(2) Thermosafe® has a validated small (Igloo® brand style [BC15] and a large [MC 50]) cooler for blood transport with a detailed packing protocol.

(3) Reference: American Red Cross JOB AID, BSD73.200M\JA02 (8/04).

Q: Is the temperature measurement thermometer important?

A: For validation(4) of Safe-T-Vue 6, Safe-T-Vue 8, and Safe-T-Vue 10, we suggest using thermister electronic thermometers and probes(5) inside simulated blood bags(6) (±0.1°C stated accuracy). Avoid surface measurement such as infrared thermometers (±1.5°C typical stated accuracy) or a glass thermometer in contact with only the surface of the bag.

(4) DigiSense is one source for thermister thermometer and appropriate immersion probes.

(5) For a detailed validation protocol, visit our web site at www.williamlabs.com, go to “References and Documents”, then download QAP 0300 incoming inspection protocol for the Safe-T-Vue product you are using (Call Customer Service at 800/767-7643).

(6) Simulated blood bags may be prepared using the appropriate volume of water with 10% glycerol by volume or Copper Sulfate-similar solution. Reference: *Technical Manual, American Association of Blood Banks*.

Q: How long can the indicators remain on stored units once applied?

A: Safe-T-Vue indicators may remain on units as long as the red color has not been observed. The indicator should always be on an area of the bag where there is the greatest mass of blood component during storage and transport.

Q: How can I be certain our blood bags are uniformly the same temperature in our refrigerator?

A: Uniform temperature of all blood bags in any given refrigerator depends on the recovery rate of the refrigerator and air circulation. One way to assist a refrigerator with cooling of blood bags is to be certain the bags are stored in a vertical position with air space around them. Bags lying on top of each other require longer times to reach refrigerator temperature.

Color Change Interpretation

When using Safe-T-Vue 6, Safe-T-Vue 8, and Safe-T-Vue 10, it is important to properly interpret Safe-T-Vue’s color change as follows:

1. The color change may take place over about 1°C ending at Safe-T-Vue indicating temperature.

(Refer to the lot specific Quality Assurance(7) document included with each shipment.)

(7) Lot specific Quality Assurance documents can be found on our web site; go to www.williamlabs.com, then “Documents and References” and select the lot you require.

2. Temperature has been reached ONLY when the entire white area is colored rose to red(8).

(8) Sometimes a pinkish hue or cast can be observed in the white disk at the start. THIS IS NOT A TEMPERATURE CHANGE. Depending upon the light source, it is a muted refraction of the bottom red disc. It is clearly distinguishable from the color change of rose to red. Use of a positive control is recommended to ensure correct interpretation.

3. The start of the color change is typically in spots of light rose to red anywhere in the white area, but is not completed until the white area has turned to red.

4. When you observe a red color indication but are certain the blood or temperature-sensitive product being monitored is below the color-indicating temperature of the Safe-T-Vue product you are using, please review the following list of actions and/or environmental factors to determine what may be causing the red indication:

a. Handling of Safe-T-Vue at the Wrong End– Indicator should be handled ONLY by the round, color-coded label end. Safe-T-Vue is extremely sensitive to its environment and touching or grasping the red end of the indicator will usually result in activation of the temperature-sensitive materials contained in Safe-T-Vue.

b. Improper Activation–when activating, be sure to press ONLY the white, color-coded round label end into the red end. Pressing directly on the red end may cause activation.

c. Premature Removal of Paper/Foil Lid–peel the paper/foil lid ONLY after attaching the Safe-T-Vue Temperature Indicator to the blood bag or temperature-sensitive product being monitored. Peeling before attachment may cause activation.

d. Excessive Time Taken to Activate–for Safe-T-Vue 8 and Safe-T-Vue 10, activation should occur within 15 seconds from the time Safe-T-Vue is removed from the refrigerator. Refer to separate instructions for activating Safe-T-Vue 6. Use of a cold pack will help maintain temperature of blood during dispensing process by placing cold pack under bag. Keep multiple cold packs in blood refrigerator to assure cold pack temperature to be same as blood bag.

e. Busy Refrigerator–check door counts since an increase of 3 to 4°C can take place in the air temperature of a blood refrigerator held open for 30 seconds.

f. Location in Refrigerator–a high door count blood refrigerator may warm Safe-T-Vue if it is located in an area of the refrigerator where it is swept by warm room air. Safe-T-Vue should be located in a sheltered area to maintain proper start temperature.

g. Blood Not Cold Enough–blood received from a supplier is sometimes very close to 10°C on arrival. Be certain blood is cooled in the refrigerator a minimum of 90 minutes before release from the blood bank when a return is likely, such as when sending to the OR.

For additional information or questions concerning Handling and Proper Use of any Safe-T-Vue product, call toll free 800/767-7643 Monday-Friday from 8:30 am to 5 pm EST and ask for Customer Service.

William Laboratories, Inc.

5 Anngina Drive, Unit B • Enfield, CT 06082
Toll Free: 800/767-7643
860/749-1350 • Fax: 860/749-1351
E-mail: info@williamlabs.com • www.williamlabs.com

SAL/0100-2, Rev 01, 11/16/07 CE 0499