

Product Validation Procedure	Product: Safe-T-Vue® 6 [Cat. #7206-XXX]
Blood Bag Temperature Monitor	Manufacturer: William Laboratories, Inc. Enfield, CT 06082 800.767.7643 www.williamlabs.com
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1.0 Purpose of Validation. To assure a consistent method of measuring and interpreting color-related temperature change in Safe-T-Vue 6 (STV 6) when used as a temperature monitoring device on some blood products contained in flexible plastic bags when the compliance upper limit temperature is 6° C.

2.0 Scope. This procedure applies specifically to Safe-T-Vue 6 [STV 6].

3.0 Related Documents & References

3.1 *American Association of Blood Banks Standards for Blood Banks and Transfusion Services*, Current Issue, Reissue of Blood and Components.

3.2 Package insert “*Instructions & FAQs*”

3.3 William Laboratories’ CD ***Instructional & Training Videos*** for Safe-T-Vue and Trans-Vue Nonreversible Temperature Indicators

4.0 Installation Qualification (IQ)

4.1 Process Description – The measurement and interpretation of the temperature-related color change for STV 6 consists of assuring a low enough starting temperature, use of temperature measuring instruments, and correct physical handling of STV 6.

4.2 Equipment Design/Description

4.2.1 Optional Cold Pack, 18 to 21 ounce for a 350 cc bag

4.2.2 A refrigerator with temperature controlled between 1° and 3.5° C;

4.2.3 A simulated blood bag having 350 cc +/- capacity filled with the appropriate volume of 10% glycerol-water mixture to simulate blood mass and volume;

4.2.4 A calibrated glass or electronic thermometer, such as “Oakton” thermister electronic thermometer with immersion probe or equivalent; [NOTE: Data loggers that can be set for 10 seconds or less sampling and display current sample reading may be used.]

4.2.5 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.

5.0 Preparation for Temperature Measurement

5.1 Store cold pack in refrigerator at least 24 hours prior to use.

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5.2 Store simulated 10% glycerol-water blood bag with thermometer in place in refrigerator at least 24 hours prior to using

5.3 Store STV 6 (box of 50) in refrigerator at least 24 hours prior to using

6.0 Temperature Measurement

6.1 Remove one STV 6 from refrigerated box of 50;

6.1.1 Peel off the "Remove" label to expose the adhesive and attach STV 6 directly to the blood bag where there is the greatest volume of liquid and immediately above the measurement probe; DO NOT ACTIVATE. [*The STV 6 may be applied to the blood bag in the refrigerator if convenient and more efficient.*] Return to refrigerator for a minimum of 15 minutes.

6.1.2 Remove one cold pack and the bag with STV 6 attached from refrigerator. Place cold pack on lab bench and bag on top of cold pack with the thermometer positioned so that it assures temperature measurement of the 'core' temperature of the liquid mass;

6.1.3 **Activate** by stabilizing STV 6 against the bag with fingertips, then peel off the top foil lid to expose the red and white rounds;

6.1.4 Fold the white round into the red round and press firmly together by pressing only on the colored, round label.

7.0 Determining the temperature of color change.

7.1 The color change in the round white area is from white to a dark rose-red or red color.

7.2 The color change process from an all-white to and all-red color typically takes place over about 1° C.

7.3 The color change process may be described as progressive by observing in sequence:

7.3.1 Small, rose or red spots around the edges of the white area and/or within the white area;

7.3.2 Areas of rose or red spots coalescing into areas of rose-red to red color;

7.3.3 The entire white area is rose-red to red indicating attainment of 6° C; a positive control is helpful for color comparison.

7.4 Repeat process with one or more STV 6 temperature indicators until satisfied that the process will consistently produce results meeting the specifications and quality characteristics of the product.

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Critical Process Variables

1. Refrigerator temperature range;
2. Calibration of temperature-measuring instruments
3. Handling and Activation of STV 6 temperature indicators

Conditions to be Monitored

1. Storage of simulated blood bag with probe inserted and STV 6 attached 1° to 3.5° C refrigerator for a minimum of 15 minutes prior to use.
2. Training to assure consistent handling, application, and storage of blood bags with STV 6 attached.