SUBJECT: IQ Validation Procedure for • Safe-T-Vue® 10 (Product No. 7201) • Safe-T-Vue® 8 (Product No. 7208)	Suggested IQ Validation
	REV 0
	Effective Date: 11/01/2012
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1.0 Purpose. To assure a consistent method of measuring and interpreting color-related temperature change in STV 10 when used as a temperature monitoring device on blood products contained in flexible plastic bags.

1.1. When the compliance upper limit temperature is 10° C [Safe-T-Vue 10];

1.2. When the compliance upper limit temperature is 8C [Safe-T-Vue 8].

2.0 Scope

This procedure applies specifically to Safe-T-Vue 10 and Safe-T-Vue 8 temperature indicators, Items 7201 and 7208, respectively. NOTE: The following Validation Procedure uses 'STV 10' (Safe-T-Vue 10) terminology; STV 8 (Safe-T-Vue 8) may be interchanged with the STV 10 nomenclature since identical procedures for the two products are recommended.

3.0 Related Documents & References

3.1. William Laboratories, Inc. *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"*

3.4. Lot specific Quality Assurance Document QAP XXXX-X, Rev X received with Safe-T-Vue 8 and Safe-T-Vue 10 shipment

4.0 Installation Qualification (IQ)

4.1. Process Description – The measurement and interpretation of the temperature-related color change for STV 10 consists of assuring a low enough starting temperature, use of temperature measuring instruments, and correct physical handling of the Safe-T-Vue Temperature Indicators.

5.0 Equipment Design/Description

5.1. Cold pack, 18 to 24 ounce for a 350 cc bag, or proportionally larger or small cold pack for larger or small blood bags, respectively.

5.2. A refrigerator with temperature controlled between 1° and 6.0° C;

5.3. A simulated blood bag having 350 cc +/- capacity filled with the appropriate volume of glycerol-water mixture to simulate blood mass and volume, or outdated blood;

5.4. A calibrated glass or electronic thermometer, such as "Oakton" thermister electronic thermometer with an 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.]

5.5. The thermometer (or electronic probe) is inserted into the bag and positioned so that it is in the approximate center of the blood bag liquid to assure temperature measurement of the 'core' temperature of the liquid mass.

6.0 Preparation for Temperature Measurement

6.1. Store glycerol-water solution in blood bag or outdated blood with thermometer in place in refrigerator at least 24 hours prior to using

6.2. Store STV 10 (box of 50) in refrigerator at least 24 hours prior to using

7.0 Temperature Measurement

7.1. Remove simulated blood bag (or outdated blood unit) with temperature measurement probe from refrigerator along with one 18 to 21 ounce cold pack and place on lab bench so that blood bag is on top of cold pack;

7.2. Remove one STV 10 from refrigerator taking care to handle STV 10 by the round, color-coded end;

7.2.1. Peel off the "Remove" label to expose the adhesive and attach STV 10 directly to the blood bag where there is the greatest volume of liquid and immediately above the measurement probe;

7.2.2. **Activate** by stabilizing STV 10 against bag with fingertips and peel off the top foil lid to expose the red and white rounds;

7.2.3. **F**old the white round into the red round, then press firmly together by pressing only on the colored, round label.

8.0 Temperature Measurement

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

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

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

8.3.1. "Red Spots – Random". Small, rose or red spots around the edges of the white area and/or within the white area;

8.3.2. "Red Filling In". Areas of rose or red spots coalescing into areas of rose-red to red color;

8.3.3. "Full Red". The entire white area is rose-red to red indicating attainment of **8° C for STV 8** and **10° C for STV 10**; a positive control is helpful for color comparison.

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

9.0 Data Collection and Management

9.1. Data may be collected on data sheet, recording:

9.1.1. The calibration correction of the electronic probe/thermometer used;

9.1.2. Visual change as described in 8.3.1, 8.3.2, and 8.3.3 as "Red spots – Random", "Red Filling In", and "Full Red Color" respectively in the spaces provided.

10.0 Critical Process Variables

1. Refrigerator temperature range
2. Calibration of temperature-measuring instruments
3. Handling of samples

11.0 Conditions to be Monitored

1. Storage of STV 8 and STV 10 in refrigerator so that 'warm air wash' from normal opening and closing of the door does not warm the indicators to above 10° C prior to use.
2. Training to assure consistent handling and application of STV 8 and STV 10.

Suggested Format for Data Collection

LOT #_____; DATE REC'D_____; NUMBER OF BOXES REC'D_____

TESTED BOX ID_____

Safe-T-Vue IQ Validation	**Sample # 1**	**Sample # 2**	**Sample # 3**
Observations	Temp. °C	Temp. °C	Temp. °C
Red Spots – Random			
Red Filling In			
Full Red			