



Protecting Patients • Reducing Risk™

Urgent Field Safety Notice

Safe-T-Vue 6 and Safe-T-Vue 10

FSCA-2016-02-18

Device Modification

2016-02-18

Attention Customer:

This letter contains important information concerning Safe-T-Vue 6 and Safe-T-Vue10. A list of affected lots is attached.

Temptime has identified incorrect information in Safe-T-Vue's instructions for use. The instructions on the box and package insert state that indicators must be removed from refrigeration and brought to room temperature every 3 months. Temptime conducted additional testing and determined that **Safe-T-Vue indicators must be removed from refrigeration for 24 to 48 hours every 2 months**. Storing Safe-T-Vue in refrigerated conditions for greater than 2 months may lead to failure of the indicator to change color when the specified temperature has been reached; potentially leading to transfusion of blood that has exceeded the temperature limit. Temptime is aware of a single product failure and complaint associated with this problem, with no adverse health events reported. Although this issue has not resulted in any reported adverse events, Temptime is committed to improving public health and is taking this action to reduce any potential risk.

What to do with Safe-T-Vue Indicators

Safe-T-Vue indicators may still be used to monitor blood bag temperature; however the instructions for use are being updated to require that users remove the indicators from refrigeration after 2 months rather than 3 months. If your usage pattern for Safe-T-Vue does not include refrigerated storage of the indicators for longer than 2 months, this change should not affect you. Revised storage instructions are as follows, with the changes highlighted in ***bold and italics***

Storage:

- Safe-T-Vue must be refrigerated at the same temperature as the blood for a minimum of 24 hours prior to use. It is suggested that boxes of Safe-T-Vue indicators be kept in the blood bank refrigerator.
- Safe-T-Vue inventory may be stored or shipped at room temperature.
- Safe-T-Vue may be kept in the blood bank refrigerator for up to **2** months. After **2** months, remove Safe-T-Vue from the refrigerator for 24 - 48 hours, and then return to the blood bank refrigerator. This cycling may be repeated every **2** months.

Please discard the instructions for use insert included with your box of Safe-T-Vue indicators and replace with the attached instructions for use. New lots of Safe-T-Vue will include revised labeling requiring removal from refrigeration after 2 months.

Safe-T-Vue indicators that have been stored in refrigerated conditions for more than 2 months may still be used, but must be cycled to room temperature for 24 - 48 hours before being returned to refrigeration and issued with blood bags.

Additional Action Required

- Please provide this Urgent Field Safety Notice to the appropriate medical staff at your institution responsible for issuing Safe-T-Vue indicators.
- Complete the attached Acknowledgement and Receipt Form, including your name, title, telephone number, email address and signature in the spaces provided.
- Send a copy of the completed Acknowledgement and Receipt Form to Temptime Corporation by fax, email, or mail:
 - Fax: +001 973-630-6100
 - Scan/email: RobertM@temptimecorp.com
 - Mail: Temptime Corporation, 116 The American Rd, Morris Plains, NJ 07950 USA

If you have questions, please contact Robert M. Molinaro, RAC at 973-630-6044 or RobertM@Temptimecorp.com Monday through Friday, 8:00 AM to 4:30 PM, Eastern Time.

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.



Steve Feldman
Vice President of Quality Assurance and Regulatory Affairs
Temptime Corporation

Urgent Field Safety Notice
Acknowledgement and Receipt Form:
 Response is Required

Safe-T-Vue 6 and Safe-T-Vue 10

Affected Product Information		
Product Name	Part Number	Lot Number
Safe-T-Vue 6	7206	S6 102615
Safe-T-Vue 6	7206	S6 011315
Safe-T-Vue 6	7206	S6 090914
Safe-T-Vue 6	7206	S6 070914
Safe-T-Vue 6	7206	S6 021814
Safe-T-Vue 10	7201	S10 112315
Safe-T-Vue 10	7201	S10 091815
Safe-T-Vue 10	7201	S10 051315
Safe-T-Vue 10	7201	S10 032615
Safe-T-Vue 10	7201	S10 021015
Safe-T-Vue 10	7201	S10 120814
Safe-T-Vue 10	7201	S10 111314
Safe-T-Vue 10	7201	S10 101314
Safe-T-Vue 10	7201	S10 082114
Safe-T-Vue 10	7201	S10 062414
Safe-T-Vue 10	7201	S10 053014
Safe-T-Vue 10	7201	S10 050514
Safe-T-Vue 10	7201	S10 040214

I have read and understand the correction instructions provided in the 2016-02-18 letter:	Yes <input type="checkbox"/> No <input type="checkbox"/>
I am aware of adverse events associated with this correction:	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, please explain:	
Signature of Receipt	
Name (print)	
Title	
Phone number	
Email address	

Send a copy of the completed Acknowledgement and Receipt Form to Temptime Corporation

- Fax: +001 973-630-6100
- Scan/email: RobertM@temptimecorp.com
- Mail: Temptime Corporation, 116 The American Rd, Morris Plains, NJ 07950 USA