URGENT SAFETY ALERT

This **Safety Alert** calls attention to a safety aspect of the CDI® H/S Cuvette.

Attention:	**Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services; Risk Management**
Affected Product:	**CDI® H/S Cuvette**
Reference Number:	**MD-2015-004-C**
Effective Date:	**December 11, 2015**

REASON FOR CORRECTION

This Safety Alert calls attention to a situation that may arise with the CDI® H/S Cuvette and recommends how to respond should the CDI® Blood Parameter Monitoring System 500 display the error message "H/S DISCONNECT AT CUVETTE."

Terumo Cardiovascular Systems (Terumo CVS) has received complaints of the CDI System 500 monitor displaying the "H/S DISCONNECT AT CUVETTE" error message when the CDI H/S Cuvette does not make a proper connection to the CDI H/S Probe. In this situation, blood parameter values for HCT, Hgb, and SO_2 do not display.

Terumo CVS has determined that this issue originated from a supplier process related to a component of the CDI H/S Cuvettes, and has taken corrective action.

POTENTIAL HAZARD

There are no reported injuries as a result of this issue.

If failure of the CDI H/S Cuvette connection is recognized after initiation of cardiopulmonary bypass (CPB), the clinician will have to choose between changing out the cuvette (which requires the interruption of CPB for an indeterminate amount of time) or relying on intermittent discreet blood gas analysis values to trend Hematocrit/Saturation (H/SAT) values (which may be contrary to hospital protocol).

RECOMMENDED ACTIONS

Note: This is a Safety Alert only. Terumo CVS is not requesting removal or return of product as a result of this activity.

Terumo CVS recommends:

- Upon attachment of the CDI H/S Cuvette to the CDI H/S Probe on the CDI System 500 monitor, verify that a connection is established **prior to initiating CPB**. This can be confirmed visually on the CDI System 500 monitor by placing the unit in "Operate" mode as shown below.

WHAT TO DO NEXT

Review this Urgent Safety Alert and follow the instructions in the Recommended Action section of this letter.

Note that Terumo CVS is not requesting removal or return of product as a result of this Safety Alert activity.

Upon attachment of the CDI H/S Cuvette to the CDI H/S Probe on the CDI System 500 monitor, verify that a connection is established **prior to initiating CPB**. If the connection is not successful, replace the CDI H/S Cuvette using aseptic technique.

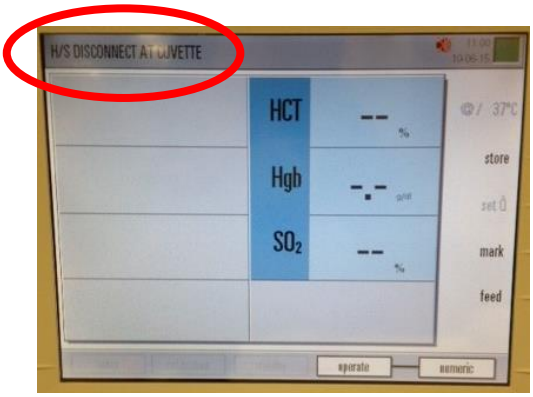
If you have questions, contact Terumo CVS Customer Service:

800.521.2818

Customer Service Hours:
Monday – Friday
8 a.m. – 6 p.m. ET

- If the CDI H/S Cuvette does not establish connection to the CDI H/S Probe (as evidenced by the "H/S DISCONNECT AT CUVETTE" error message on the CDI System 500 monitor display), try repositioning the cuvette in the probe head.
- If repositioning the cuvette in the probe head does not result in a successful connection and error-free monitor display, replace the CDI H/S Cuvette using aseptic technique.
- If you experience an "H/S DISCONNECT AT CUVETTE" error message that you are not able to resolve, follow your complaint reporting protocol and contact Terumo CVS.

How to Confirm the Cuvette-to-Probe Connection Prior to Initiating CPB:



Not Connected: *The "H/S DISCONNECT AT CUVETTE" error message displays in the upper left corner of the monitor display. This error message indicates that the CDI H/S Cuvette has not established connection to the CDI H/S Probe.*

Connected: *The CDI System 500 monitor displays a value or an indicator of "High" or "Low" in the HCT, Hgb, and SO_2 fields. There is no error message for the "H/S DISCONNECT AT CUVETTE" displayed in the upper left corner of the monitor.*

AFFECTED POPULATION

All patients requiring cardiopulmonary bypass and being monitored with a CDI System 500 using a CDI H/S Cuvette are affected.

AFFECTED PRODUCT

Catalog Number	Product Description	Dates of Distribution	Lot Number or Serial Number Range
6912, 6913, 6914, 6932, 6933, 6934	CDI H/S Cuvette, Sterile	07-May-2015 to 25-Nov-2015	See customized information on Customer Response Form included with this notice
6922, 6923, 6924	CDI H/S Cuvette, Non-sterile	05-May-2015 to 14-Oct-2015	
Various	Cardiovascular Procedure Kits containing CDI H/S Cuvettes from the affected lots	04-Jun-2015 to 08-Dec-2015	

CUSTOMER INSTRUCTIONS

1. Review this Safety Alert and the Recommended Actions.
2. Assure that all users receive notice of this issue.
3. Confirm receipt of this Safety Alert by emailing or faxing the attached Customer Response Form to the email address or fax number indicated on the form.
4. If you experience an "H/S DISCONNECT AT CUVETTE" error message that you are not able to resolve, follow your complaint reporting protocol and contact Terumo CVS.

QUESTIONS?

We encourage you to contact Terumo CVS with any questions or concerns:

- **Terumo CVS Customer Service:** 1.800.521.2818
  Monday – Friday, 8 a.m. – 6 p.m. ET
- **Recall Fax:** 1.734.741.6149

REPORTING

Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program:

- **Phone:** 1.800.FDA.1088
- **Fax:** 1.800.FDA.0178
- **Web:** www.fda.gov/medwatch/report.htm
  MedWatch Online Voluntary Reporting Form (mail to address on form):
  www.fda.gov/Safety/MedWatch/HowtoReport