TERUMO

# URGENT MEDICAL DEVICE RECALL

This is a Voluntary Recall involving the physical **Removal** of a device from its point of use.

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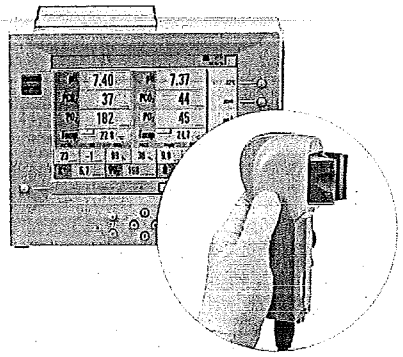
| **Attention:** | **Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services; Risk Management** |
| **Affected Product:** | **CDI® Blood Parameter Monitoring System 500, BPM Sensor Head Assembly** |
| **Reference Number:** | **AA-2016-001-R** |
| **Effective Date:** | **March 14, 2016** |



## REASON FOR REMOVAL

Specific CDI® Blood Parameter Monitoring System 500 devices are being voluntarily recalled because the BPM Sensor Head Assembly's Thermistor, which provides the blood temperature value that results in accurate display values on the monitor, does not meet specification. This may cause inaccurate temperature measurement and inaccurate analyte display values on the CDI System 500 monitor.

Terumo Cardiovascular Systems (Terumo CVS) received complaints of inaccurate temperature measurements for specific devices distributed since November 5, 2015. These include both new production devices and recently serviced devices.

## POTENTIAL HAZARD

There have been no reported illnesses or injuries as a result of this issue.

A user who is not aware that the CDI System 500 is displaying inaccurate temperature values may not manage patient temperature appropriately. Using inaccurate information to manage warming and cooling strategies for a procedure could result in prolonged time on bypass. It could also lead to unnecessarily aggressive temperature management, resulting in excessive hyper or hypothermia, with potential neurologic and organ dysfunction, or increased blood component damage.

Inaccurate temperature measurement could also cause inaccurate measurements of other BPM values including potassium ($K^+$), $pO_2$, $pCO_2$, and pH. The greater the temperature inaccuracy, the greater the degree of inaccuracy of these other BPM values due to the dependence of their algorithms on temperature for the calculations. Inaccurate measurement of these values could result in inappropriate patient management strategies being employed to address them with the potential to result in moderate patient injury.

It is likely that the user will recognize inaccurate temperature readings from the CDI System 500 due to the multiple temperature readings available from other devices in the operating room.

### WHAT TO DO NEXT

Depending on institution protocol or preference, users may choose to either:

- Stop using devices with the affected serial numbers and return the affected devices to Terumo CVS, **or**
- Continue using devices with the affected serial numbers only for HSAT monitoring functions until the replacement BPM Sensor Head Assemblies are available.

See Customer Instructions for additional information.

If you have questions, contact Terumo CVS Customer Service:

**800.521.2818**

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

The CDI System 500 Instructions for Use caution the user to verify the accuracy of displayed values with another source before initiating treatment, as well as to perform periodic comparisons of results to a laboratory reference sample. Any question about the validity of a displayed value should prompt verification with another source (i.e., laboratory or blood gas analyzer).

**It is important to note that HSAT monitoring functions are not affected by this issue.** (Hematocrit, Hemoglobin and Oxygen Saturation measures are not influenced by temperature measurement.) Continued use of HSAT monitoring when using the CDI System 500 is clinically sound and offers patient benefit. It also may be included in hospital protocol or professional society care guidelines, or considered standard of care in some settings. Terumo CVS therefore recognizes the need to provide users the two options outlined below under Correction.

## CORRECTION

Depending on institution protocol or preference, users may choose to:

- Stop using devices with the affected serial numbers and return the affected devices to Terumo CVS, **or**
- Continue using devices with the affected serial numbers only for HSAT monitoring functions until the replacement BPM Sensor Head Assemblies are available.

See Customer Instructions for additional information.

Terumo CVS Sales Representatives will keep users updated as to timing of the correction and device availability.

## AFFECTED POPULATION

Affected population includes all patients being monitored with a CDI System 500 manufactured or serviced with an affected component after November 5, 2015.

Patients undergoing cardiac procedures that require more extreme temperature modification will incur the greatest opportunity for temperature-related inaccuracies (for example, pediatric and neonatal cardiac procedures, and adult procedures using moderate levels of hypothermia and rewarming).

## AFFECTED PRODUCT

| Catalog Number | Product Description | Configuration Detail | Dates of Distribution | Serial Number Range |
|---|---|---|---|---|
| 500AHCT | CDI Blood Parameter Monitoring System 500 | With one blood parameter module and one Hct/Sat probe | November 5, 2015 through February 3, 2016 | Refer to the Affected Population on the attached Customer Response Form |
| 500AV | | With two blood parameter modules | | |
| 500AVHCT | | With two blood parameter modules and one Hct/Sat probe | | |

## CUSTOMER INSTRUCTIONS

1. Review this Medical Device Recall notice.

2. **Assure that all users have received notice of this issue, and prominently display this notice where all users may access it.**
3. Confirm receipt of this communication by completing and returning the attached Customer Response Form as indicated on the form.
4. Determine whether your institution will:

   a) **Stop using devices with the affected serial numbers and return the affected devices to Terumo CVS.**

   - Terumo CVS will issue a Returned Goods Authorization upon receipt of the Customer Response Form. An express shipping number is available on request to facilitate device return.
   - Terumo CVS will replace the BPM Sensor Head Assemblies in affected CDI System 500 devices and return the corrected devices to users after the correction is complete.
   - There is not yet a timing estimate on when the corrected BPM Sensor Head Assemblies will be available for replacement.

   ***- OR -***

   b) **Continue using devices with the affected serial numbers only for HSAT monitoring functions until the replacement BPM Sensor Head Assemblies are available.**

   - After receipt of the Customer Response Form, Terumo CVS will supply a label which must be attached to the BPM Sensor Head Assembly to indicate that it is no longer valid for clinical use.
   - **It is essential that only the HSAT functionality be used** until either the impacted device is repaired or a loaner device is obtained, as these parameters are unaffected by temperature and therefore are immune to the issue which is the subject of this field action.
   - Terumo CVS will contact users when the corrected component is available to request the affected devices be returned to Terumo CVS for service.

Either course of action may require the user to perform more frequent blood gas analysis from a laboratory or point-of-care blood gas analyzer.

Terumo CVS Sales Representatives will keep users updated as to timing of the correction and device availability.

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## QUESTIONS?

We encourage users 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

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## 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