# Urgent FIELD SAFETY NOTICE

Device: **Terumo® CDI® Blood Parameter Monitoring System 500, BPM Sensor Head Assembly**

Reference: **FSN 1509 2016-04**

Action: **Removal**

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**Attention:** Chief of Perfusion; Department of Cardiovascular Surgery; Director of Operating Room Services; Director of Biomedical Services; Risk Management

## DESCRIPTION OF THE PROBLEM

Specific CDI® Blood Parameter Monitoring System 500 devices are being voluntarily recalled because the **B**lood **P**arameter **M**odule (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.

## DETAILS ON AFFECTED DEVICES

The affected population is limited to devices serviced or distributed from November 5, 2015 through February 3, 2016.

Refer to the exact Affected Population on the enclosed annex.

There are no other serial numbers involved.

Some of the CDI System 500 monitors from the list in annex can contain one BPM which is not impacted by this issue. Any BPM unit not listed in the table can be further used being not affected.

## POTENTIAL HAZARD

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.
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 corrective action.

## CORRECTIVE ACTION

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 Europe, **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 Representatives will keep users updated as to timing of the correction and device availability.

## CUSTOMER INSTRUCTIONS

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

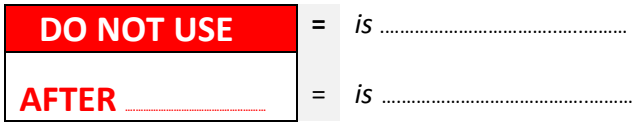
   a) **Stop using devices with the affected serial numbers and return the affected devices to Terumo Europe.**

   - Terumo Europe will arrange the return of the device.
   - Terumo Europe 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.**

   - Attach the supplied label (see example below) to each affected BPM Sensor Head Assembly to indicate that it is no longer valid for clinical use.




**Example label for affected BPM**

- **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 Europe will contact users when the corrected component is available to request the affected devices be returned 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 Representatives will keep users updated as to timing of the correction and device availability.

We confirm that this *Field Safety Notice* has also been notified to your national Competent Authority.

We encourage you to contact us or your local Terumo representative with any questions or concerns.

Organisation (to be completed by the sales or dealer)
Contact name (function)
Contact phone, mobile, email

[redacted]

Terumo Europe NV
Leuven, Belgium

## ANNEX - AFFECTED POPULATION

**Affected BPM Serial number(s) mounted in affected CDI System 500 monitors**

Some of the CDI System 500 monitors from the list below can contain one BPM which is not impacted by this issue. Any BPM not listed in the table below can be further used being not affected.

| CDI500 Code | CDI500 Serial number | BPM Serial number | CDI500 Code | CDI500 Serial number | BPM Serial number |
|---|---|---|---|---|---|
| 500AHCT | 1137 | B019851 | 500AVHCT | 2243 | B019969 |
| 500AHCT | 1843 | B021236 | 500AVHCT | 2365 | B021220 |
| 500AHCT | 1997 | B021266 | 500AVHCT | 2374 | B021234 |
| 500AHCT | 2032 | B021213 | 500AVHCT | 2377 | B020022 |
| 500AHCT | 2207 | B019871 | 500AVHCT | 2377 | B020023 |
| 500AHCT | 2207 | B021239 | 500AVHCT | 2543 | B021202 |
| 500AHCT | 2717 | B019807 | 500AVHCT | 2543 | B021211 |
| 500AHCT | 2718 | B021260 | 500AVHCT | 2588 | B019811 |
| 500AHCT | 3059 | B021131 | 500AVHCT | 2601 | B021147 |
| 500AHCT | 3106 | B021270 | 500AVHCT | 2601 | B021148 |
| 500AHCT | 3187 | B019941 | 500AVHCT | 2629 | B021144 |
| 500AHCT | 3555 | B021149 | 500AVHCT | 2629 | B021146 |
| 500AHCT | 3556 | B019791 | 500AVHCT | 2669 | B019850 |
| 500AHCT | 3567 | B021142 | 500AVHCT | 2669 | B020024 |
| 500AHCT | 4004 | B021237 | 500AVHCT | 2757 | B021134 |
| 500AHCT | 5105 | B021235 | 500AVHCT | 2837 | B019812 |
| 500AHCT | 5151 | B019848 | 500AVHCT | 2837 | B019813 |
| 500AHCT | 5209 | B019961 | 500AVHCT | 2893 | B021238 |
| 500AHCT | 5266 | B019971 | 500AVHCT | 2980 | B021132 |
| 500AHCT | 5266 | B020021 | 500AVHCT | 3009 | B021199 |
| 500AHCT | 5709 | B019889 | 500AVHCT | 3010 | B019967 |
| 500AHCT | 5749 | B021130 | 500AVHCT | 3153 | B019872 |
| 500AHCT | 5750 | B019849 | 500AVHCT | 3182 | B021267 |
| 500AHCT | 5785 | B021221 | 500AVHCT | 3182 | B021268 |
| 500AHCT | 5788 | B021215 | 500AVHCT | 3390 | B019810 |
| 500AHCT | 7143 | B021139 | 500AVHCT | 3422 | B019784 |
| 500AHCT | 7260 | B019890 | 500AVHCT | 3422 | B019885 |
| 500AVHCT | 1052 | B019959 | 500AVHCT | 3422 | B019886 |
| 500AVHCT | 1052 | B019960 | 500AVHCT | 3605 | B021145 |
| 500AVHCT | 1052 | B019968 | 500AVHCT | 3607 | B021261 |
| 500AVHCT | 1427 | B019884 | 500AVHCT | 3607 | B021262 |
| 500AVHCT | 1697 | B020020 | 500AVHCT | 4099 | B019808 |
| 500AVHCT | 1697 | B020025 | 500AVHCT | 4099 | B019809 |
| 500AVHCT | 1857 | B019887 | 500AVHCT | 4262 | B021133 |
| 500AVHCT | 1857 | B019888 | 500AVHCT | 4344 | B019869 |
| 500AVHCT | 1903 | B019970 | 500AVHCT | 4344 | B019870 |
| 500AVHCT | 1928 | B019783 | 500AVHCT | 5242 | B021141 |
| 500AVHCT | 1958 | B019814 | 500AVHCT | 5520 | B021201 |
| 500AVHCT | 1970 | B019957 | 500AVHCT | 5520 | B021264 |
| 500AVHCT | 1972 | B021259 | 500AVHCT | 5520 | B021265 |
| 500AVHCT | 1984 | B019939 | 500AVHCT | 5762 | B019790 |
| 500AVHCT | 1984 | B019940 | 500AVHCT | 7250 | B021219 |
| 500AVHCT | 1984 | B019958 | | | |

| CDI500 Code | CDI500 Serial number | BPM Serial number | CDI500 Code | CDI500 Serial number | BPM Serial number |
|---|---|---|---|---|---|
| 500AHCT | 8004 | All | 500AHCT | 8030 | All |
| 500AHCT | 8005 | All | 500AHCT | 8033 | All |
| 500AHCT | 8014 | All | 500AHCT | 8036 | All |
| 500AHCT | 8015 | All | 500AHCT | 8038 | All |
| 500AHCT | 8017 | All | 500AHCT | 8055 | All |
| 500AHCT | 8019 | All | 500AVHCT | 8022 | All |
| 500AHCT | 8021 | All | 500AVHCT | 8024 | All |
| 500AHCT | 8025 | All | 500AVHCT | 8037 | All |
| 500AHCT | 8027 | All | 500AVHCT | 8066 | All |
| 500AHCT | 8029 | All | 500AVHCT | 8067 | All |

**Reference Device Code and Description**

| Catalog Number | Product Description |
|---|---|
| 500AHCT | CDI Blood Parameter Monitoring System 500 With one blood parameter module and one Hct/Sat probe |
| 500AVHCT | CDI Blood Parameter Monitoring System 500 With two blood parameter modules and one Hct/Sat probe |

# *Field Safety Notice* - CUSTOMER REPLY FORM

Device: **Terumo® CDI® Blood Parameter Monitoring System 500, BPM Sensor Head Assembly**

Reference: **FSN 1509 2016-04**

Action: **Removal**

**Please complete, sign and e-mail or fax this back**: To:

E-mail/Telefax:

| | |
|---|---|
| **Client number** | |
| **Hospital Name** | |
| **City** | |
| **Country** | |

**Our records indicate that you have received devices from the affected population.**

**By completion and return of this form, I am confirming receipt, reading and acting on this Safety Notice:**

☐ **We continue using devices with the affected serial numbers only for HSAT monitoring functions and we have attached the supplied label to the affected BPM Sensor Head Assembly to indicate that it is no longer valid for clinical use. We have labelled the following units:**

| CDI500 Code | Serial number - CDI500 | Serial number (s) - BPM |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

**- OR -**

☐ **We have stopped using the devices with the affected serial numbers and the following affected units ready to return:**

| CDI500 Code | Serial number - CDI500 | Serial number (s) BPM | Number of units ready to return |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

| | |
|---|---|
| **Person Responding [Please Print]** | |
| **Title** | |
| **Phone Number** | |
| **Signature** | |
| **Date** | |

**FSN1509A** [EN]