

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 01/04/2010 - 03/29/2010*
	FEI NUMBER 1828100

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mark A. Sutter, President and Chief Executive Officer

FIRM NAME Terumo Cardiovascular Systems Corporation	STREET ADDRESS 6200 Jackson Road
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CITY, STATE, ZIP CODE, COUNTRY Ann Arbor, MI 48103-9586	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer
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This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Your firm is a manufacturer of a variety of class II and class III cardiovascular surgical devices used during cardiopulmonary bypass procedures. These cardiovascular surgical devices include, but are not limited to: Heart-lung machine consoles (Advanced Perfusion System 1 (APS-1), 8000 Perfusion System, and 9000 Perfusion system), CDI500 blood parameter monitors (CDI500) and CDI510H disposable sensors, air bubble detector systems (ABD), HX2 temperature management systems (HX2) used for blood and cardioplegia temperature regulation, roller-type (large and small) and non-roller-type blood pumps (centrifugal), endoscopic vein harvesting systems, electronic patient gas system (EPGS) oxygen sensors, and vascular cannula and catheters.

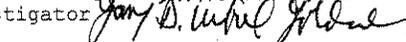
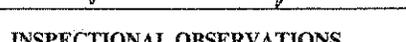
MANAGEMENT CONTROLS

OBSERVATION 1

Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization.

Specifically, your firm has not implemented an adequate and effective quality system at all levels of your organization. Quality System requirements have not been completely established in the areas of Corrective and Preventive Actions (CAPA) to include Medical Device Reports (MDR) and Complaint Handling, Production and Process Controls, and Purchasing Controls (refer to the observations below).

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CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)

OBSERVATION 2

Certain indicators of nonconformities are not investigated to determine the cause of the nonconformity.

Specifically:

- A. The cause of non-conformities relating to product has not been fully investigated. Two corrective actions were opened at the Terumo Cardiovascular Systems location in Tustin, California regarding potassium measurement inaccuracies during cardiopulmonary bypass associated with the CDI500 blood parameter monitor and CDI510H disposable sensors. The corrective action associated with the possible failure of the user to enter the correct potassium code for the CDI510H disposable sensor is addressed in Tustin CA-00145. The corrective action and associated investigation for potential design issues regarding the CDI500 monitor was initiated per Tustin investigation TU-40001. In May 2009, investigation TU-40001 was transferred to Terumo Cardiovascular Systems in Ann Arbor, Michigan and CAPA determination CD-00083 was opened in Ann Arbor. The decision was made by personnel in Ann Arbor to monitor the complaints of potassium inaccuracies and no CAPA was initiated to continue the activities started in TU-40001. A complete root cause has not been determined for the observed potassium inaccuracies associated with the CDI500 monitor, which continues to be manufactured and distributed.
- B. Your firm has not implemented corrective and preventive actions related to workmanship issues from your supplier of printed circuit boards (PCB). On 12/16/2004, your firm created Corrective Action 391 to address an "on-going workmanship issue" related to your supplier of printed circuit boards (PCB) due to flux and other contamination issues along with other known workmanship issues. Corrective Action 391 was subsequently closed by your firm on 3/30/2005.

On 7/5/2006 your firm created preventive action 155 (PA 155) to address solder, flux contamination, and corrosion issues on all applicable APS-1, 8000, and 9000 perfusion system PCBs. At this time it was determined to switch from (b) (4)

On 3/29/2007 your firm determined to (b) (4)
(b) (4)

On 4/2/2008 an extension to PA 155 was approved due to the decision to (b) (4) On 12/5/2008 your firm also created PA 304 which also addressed transferring all (b) (4)

(b) (4) On 6/25/2009 your firm combined PA 155 and PA 304 into PA-00005-SS which is now under your new

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CAPA data management system (b) (4).

As of 3/18/2010, PA-00005-SS has not been implemented and your firm is still (b) (4) that was first identified on 12/16/2004 and later on 7/5/2006 as having workmanship issues. Currently your firm receives (b) (4) different PCBs from this one supplier. These PCBs are used in many of your firm's medical devices including, but not limited to 4" and 6" roller pumps, HX2, ABD, and CDI-500 devices. As of 3/18/2010, your firm has only (b) (4) Risk assessment (b) (4) (created 5/2/2006) states that workmanship issues for PCBs manufactured by your supplier has a (b) (4). Your firm has recently initiated nonconformance reports (NCR) that refer to (b) (4). These NCRs include NCR 6993 (received 2/1/2010), NCR 6972 (received 1/27/2010), and NCR 6433 (received 8/31/2009).

- C. Your firm received complaint CR-15947 on 11/9/2009 in which your customer stated a patient died after your firm's Soft Flow Arterial cannula (part number 4984, lot number 0556925) was removed from a patient at which time a clot was found entangled in the diffuser tip of the cannula. Your firm did not document the attempts to retrieve the product from the hospital, or document the reason why no products were returned for investigation. The investigation conducted by your firm did not include any attempts to try and recreate the problem on the remaining inventory in stock (only a visual inspection of the remaining stock was conducted. The investigation did not determine if your firm's product caused or contributed to the patient's death. Your firm's Director of Clinical Support documented that blood samples were collected by the hospital/customer for analysis; there is no documentation for this complaint investigation regarding the results of the blood analysis or attempts to obtain this or any other clinical information. (Refer to Observation 9D)
- D. Your firm has conducted incomplete investigations in that your firm has not investigated the cause of nonconformities of your firm's Air Bubble Detection (ABD) system that have occurred on your firm's heart-lung consoles, models 8000 and APS1. For example, your firm has not determined the cause of six (6) of twenty-three (23) complaints received by your firm between 03/28/2008 and 11/11/2009 (CR-14736, CR-14267, CR-13986, CR-12132, CR-11909, and CR-11052) alleging ABD system failures in the field that include false air emboli detection alarms, the inability to reset ABD systems, and causing arterial pumps to stop during bypass surgery. Included in these six (6) complaints are:
- i. Complaint Document # CR-14267 of 05/11/2009, reporting, "Air bubble detection went off during case with no air being present. Could not reset air detection, so perfusionist started pulling connection and hand cranking until the pump started running." Your firm was not able to duplicate this alleged ABD system failure, and subsequently concluded that "due to a root cause of could not duplicate, no CA or PA recommended for this complaint."

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- ii. Complaint Document # CR-14736 of 06/30/2009, reporting that "the air bubble detection alarmed although air was not present, resulting in an alarm with a primed circuit in a static mode that was not pumping." Your firm was not able to duplicate this alleged ABD system failure, and subsequently concluded, "Root Cause: Could not duplicate. No CA or PA is necessary. This is a low risk issue."
 - iii. Complaint Document # CR-11052 of 03/28/2008, reporting, "Air sensor alarms and shuts off the pump even when there's plenty of fluid and no air in the system." Your firm documented that your firm's "Field Service rep indicated that he did ship parts back however no record of parts being received by service department. Root Cause designated as 'No Product Available'."
- E. On or about 4/1/2008 your firm approved the HX2 Temperature Management System (HX2) for sale. On 1/15/2009 your firm received its first complaint (CR-13325) regarding a failure related to the mixing valve of the HX2 which made one of the two channels of the device fail. On 3/31/2009 your firm received its eighth complaint (CR-13963) regarding the same failure of the mixing valve. On 3/31/2009 your firm launched a correction to this failure. However, your firm did not fully investigate the root cause of these failures prior to implementing this correction. For example, one of your firm's Quality Engineers stated the initial root cause investigation determined the HX2 (b) (4). The investigation activities and results of the investigations were not documented including the (b) (4). As a result of the investigation a (b) (4) was implemented on 3/31/2009. Your firm received an additional seven (7) complaints related to the same type of failure after the launch of this correction on 3/31/2009.
- Your firm later determined the failure of these HX2s was (b) (4). According to CAPA 8D-00273 (created 8/3/2009) an investigation had been initiated in July 2009 around the time your firm received complaint CR-14743 (the last of the seven complaints mentioned above). Your firm manufactured and distributed approximately (b) (4) HX2s prior to determining the root cause of the mixing valve failure noted in CAPA 8D-00273.
- F. CAPA #8D-00227 of 6/21/09 was moved from the Root Cause Analysis phase to the Develop Action Plan phase even though the Root Cause evaluation did not extend beyond the determination that "electrical overstress" was the cause of the failures.
- Failures of the (b) (4) brand digital displays (Terumo part 801224) used in small and large roller pumps and centrifugal pumps utilized as part of your firm's APS-1 heart-lung machines have generated a series of CAPAs because of malfunctions of these displays. A series of CAPAs have been initiated including #8D-00227 of 6/21/09 to address these failures. This particular CAPA contains an incomplete Root Cause evaluation that has now moved to the Action Plan stage even though there is no definitive Root Cause.
- The current action plan includes a design change (b) (4)

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(b) (4)

The proposed validation testing of this change to the **(b) (4)** **(b) (4)** has not been proven to induce the subject failures in the **(b) (4)** **(b) (4)**

OBSERVATION 3

Not all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified.

Specifically, the following events occurred:

- A. Your firm has not identified all of the actions needed to correct and prevent the recurrence of nonconformities of your firm's Air Bubble Detection (ABD) system (ABD Ultrasonic Air Sensor (UAS), LEMO cable, safety monitor, ABD module) that have occurred on your firm's heart-lung devices, models 8000, 9000, and APS1. These device failures, which include intermittent or continuous false air emboli detection alarms, the inability to reset ABD systems, and causing arterial pumps to stop during bypass surgery, were addressed by your firm through the approved implementation of sixteen (16) corrective and preventive actions (CAPAs) between 06/28/2006 and 10/29/2009, one (1) field correction between 2006 and 2007 to upgrade ABD module software (1828100-03/01/2006-026-C), and one (1) international and domestic recall between 2007 and 2008 of more than **(b) (4)** ABD UAS devices (Z-530/532-2008). These actions are:

Action	Action #	Action addresses	Date Created	Final Approval Date
Corrective Action	CA 33, Rev. (b) (4)	ABD UAS failures	08/26/2005	06/28/2006
Corrective Action	CA 33, Rev. (b) (4)	ABD UAS failures	03/13/2007	09/07/2007
Corrective Action	CA 33, Rev. (b) (4)	ABD UAS failures	01/16/2008	01/29/2008
Preventive Action	PA 88, Rev. (b) (4)	LEMO cable failures	12/21/2005	06/29/2007
Preventive Action	PA 88, Rev. (b) (4)	LEMO cable failures	08/27/2007	04/09/2009
Preventive Action	PA 118, Rev. (b) (4)	ABD module failure	03/07/2006	11/13/2006
Corrective Action	CA 132, Rev. (b) (4)	ABD UAS failures	04/04/2006	10/11/2006
Corrective Action	CA 132, Rev. (b) (4)	ABD UAS failures	09/16/2007	11/27/2007
Corrective Action	CA 138, Rev. (b) (4)	LEMO cable failures	04/26/2006	01/09/2007
Corrective Action	CA 138, Rev. (b) (4)	LEMO cable failures	01/10/2007	04/26/2007
Preventive Action	PA 155, Rev. (b) (4)	ABD module failures	07/05/2006	04/02/2008
Preventive Action	PA 155, Rev. (b) (4)	ABD module failures	04/02/2008	Transferred to PA-00005-SS
Preventive Action	PA-00005-SS	ABD module failures	06/25/2009	Open
Preventive Action	PA 287, Rev. (b) (4)	ABD module failures	07/02/2008	09/23/2008
Corrective Action	CA 293, Rev. (b) (4)	ABD UAS failures	07/21/2008	07/14/2009

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Action	Action #	Action addresses	Date Created	Final Approval Date
Corrective Action	CA 323, Rev. (b)(4)	ABD UAS failures	02/27/2009	10/29/2009
Supplier Corrective Action	N3770, Rev. (b)(4)	LEMO cable failures	01/03/2008	02/29/2008
Supplier Corrective Action	N4210, Rev. (b)(4)	LEMO cable failures	03/19/2008	08/05/2008
CAPA Determination	CD-00017	LEMO cable failures	04/19/2009	No CAPA implemented
CAPA Determination	CD-00018	LEMO cable failures	04/20/2009	No CAPA implemented
CAPA Determination	CD-00154	ABD UAS failures	07/13/2009	Open
CAPA Determination	CD-00198	ABD UAS failures	07/28/2009	Open
CAPA Determination	CD-00245	ABD module failures	09/10/2009	Open
Field Correction	1828100-03/01/2006-026-C	ABD module failures	10/04/2006	Closure report to FDA on 10/19/2007
Recall	Z-530/532-2008	ABD UAS failures	06/14/2007	Closure report to FDA on 08/06/2008

However, your firm has not identified all of the actions needed to correct or prevent the recurrence of these ABD system nonconformities. For example, from 08/13/2008 to 06/30/2009, your firm received complaints CR-14267, CR-14736, and CR-12132 alleging ABD system alarms with no air present (an alleged false alarm). The approved implementation of the aforementioned sixteen (16) CAPAs, one (1) software field correction, and one (1) recall did not correct or prevent the recurrence of the alleged false alarms in complaints CR-14267, CR-14736, and CR-12132; no root cause has been determined for these alleged false alarms; and as of the date of this inspection, no corrective or preventive action has been implemented regarding these complaints to correct or prevent the recurrence of these alleged false alarms.

- B. CAPA #8D-00285 of 8/16/09 (TCVS APS-1 Roller Pump Software issues) identified that pump starts, stops, and speed jumps may be caused by software issues. While your firm knew of these software issues as long ago as 2006, the firm has not changed its roller pump software to address this problem as of the date of the current inspection.

On 8/8/2006 your firm identified software issue # (b)(4) (now identified as issue # (b)(4)) that detected uninitialized variables within the APS-1 small roller pump software that could cause the pump to reset or stop before/during a procedure.

Your firm updated risk assessment of 8/18/09 which classifies this problem as "Broadly Accepted" in part due to the lack of serious injury at the time of the reported malfunctions.

Your firm continues to produce and distribute large and small roller pumps with distribution of (b)(4) of these pumps in 2010.

- C. CAPA #8D-00132 of 4/29/09 fails to address the difference between the vendor's expiration specification of (b)(4) (b)(4) hours minimum for their (b)(4) oxygen sensor and your firm's specification that says this same replaceable

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oxygen sensor is good for (b) (4) hours.

CAPA #8D-00132 was opened to address malfunctions of the Electronic Patient Gas System (EPGS) due to failures of the internal replaceable oxygen sensor component (b) (4) of this EPGS. The EPGS provides control and monitoring of the gas flow rate and oxygen content of the gas input to the oxygenator in the perfusion circuit as an optional subsystem for use on your firm's APS-1 heart-lung machine. While this CAPA identified that, (b) (4) (b) (4), this same investigation does not resolve the difference between the vendor's specification (b) (4) and your firm's specification of (b) (4) % hours.

Premature failure of this (b) (4) oxygen sensor (as used within the Terumo APS-1/EPGS) is a confirmed source of complaints such as #CR-15652 of 10/7/09. This complaint was confirmed as valid with failure of this sensor after (b) (4) % hrs. This is equivalent to approximately (b) (4) % of the useful life specified by your firm for this sensor.

Your firm continues to produce and distribute this EPGS with distribution of (b) (4) of these units between 4/17/09 and 2/19/2010.

OBSERVATION 4

Corrective and preventive actions have not been verified or validated to ensure that the action is effective and does not adversely affect the finished device.

Specifically, corrective actions were not effective. Notice of Field Correction NFC 818019 was implemented between 7/15/2008 and 6/11/2009 to address recalls Z-0354-2009, Z-0355-2009, Z-0356-2009, and Z-0357-2009 regarding grease leakage from the motor bearing onto the optical encoder on the APS1 roller pump used in cardiopulmonary bypass. Grease leakage was determined to be the cause of underspeed/overspeed errors and erratic pump behavior. The activities noted in notice of field correction NFC 818019 were not implemented correctly in approximately 11 confirmed instances in which overspeed/underspeed errors and erratic pump behavior occurred after the field correction was performed.

Additionally, the corrective actions contained in NFC 818019 were not adequately validated. Validation activities were performed in the service department at Terumo Cardiovascular Systems with two roller pumps removed from the System 1 chassis and placed on a bench. Two field service representatives serviced one roller pump each during the validation. The actual implementation of NFC 818019 in the field at the user facility was performed using a pump work stand and static mat. In various instances, the user facility had more than one pump that needed to be serviced, more than one pump was serviced on the same day, and the service was performed in less-than-ideal conditions in terms of lighting and location.

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OBSERVATION 5

Corrective and preventive action procedures addressing the use of appropriate statistical methodology to identify existing and potential causes of nonconforming product or other quality problems were not defined and implemented.

Specifically, the following instances have been documented:

- A. A quality board decision (b) (4) was made on 8/20/2009 regarding the mixing valve failures found on your firm's HX2 Temperature Management System. Part (b) (4) section (b) (4) of the related health hazard evaluation (HHE) (b) (4) calculated an occurrence rate of (b) (4)%. However, the calculation used the figure (b) (4)

(b) (4)

- B. Your firm uses statistical analysis to assign a frequency of occurrence of reported device-related events, such as complaints. For the CDI 500 Blood Parameter Monitoring System, the frequency of occurrence regarding device-related events is determined by (b) (4) (b) (4). This calculation assumes each complaint represents one event. However, in the case of potassium inaccuracies associated with the CDI500 monitor and CDI510H disposable sensor, complaint CR-11623 states potassium inaccuracies were observed in approximately twenty (20) cases and CR-10528 states potassium inaccuracies were observed in approximately three (3) cases. Complaints CR-11623 and CR-10528 represent approximately twenty-three (23) cases. According to procedure QAP007 rev. A "Management of Corrective and Preventive Actions", decisions regarding initiating product-related corrective actions are made in part by determining risk. According to work instruction (b) (4) (b) (4), document no. (b) (4), frequency of occurrence is a factor in documenting the assessment of risk.

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OBSERVATION 6

Corrective and preventive action activities have not been documented, including the verification or validation of corrective actions.

Specifically, your firm did not document that an effectiveness check of corrective action, CA # 132, Rev. (b) (4) of 11/27/2007, was conducted prior to its closure on 06/22/2009. Your firm documents that this corrective action was created to address complaint # PPR 1625, Rev. (b) (4) of 07/09/2007, which reports that an Air Bubble Detection Ultrasonic Air "Sensor won't generate alarm signal regardless of whether or not tubing is clamped in place or whether or not air is present."

OBSERVATION 7

Complaint handling procedures for receiving complaints have not been implemented.

Specifically:

- A. According to your firm's current procedure (b) (4) rev. (b) (4) "Corporate Procedure - Complaint Handling Process", (b) (4)

(b) (4) is made in section (b) (4) of (b) (4) revs. (b) (4) and (b) (4) "Corporate Procedure - Complaint Handling Process", which were in effect from

November 14, 2007 to August 18, 2008. In the case of potassium inaccuracies associated with the CDI 500 monitor and CDI 510H disposable sensor, complaint CR-11623, received June 6, 2008, states potassium inaccuracies were observed in approximately twenty (20) cases. Complaint CR-10528, received January 24, 2008, states potassium inaccuracies were observed in approximately three (3) cases. Complaints CR-11623 and CR-10528 represent approximately twenty-three (23) cases, but were only entered as two (2) complaints in your firm's (b) (4) system. Calculations for data analysis, such as trending, assume each complaint represents one event.

- B. Your firm failed to collect and document complaint/event information, to include patient follow-up questions or relevant clinical information, to determine if the failures resulted in a serious injury or device malfunction. Between the dates of 4/1/2008 (the approval for sale of the HX2) and 10/19/2009, your firm received complaints regarding the following error codes:
- i. EOE or EOD error codes (mixing valve failure): Your firm received fifteen complaints regarding mixing valve failures for your HX2 device, seven (7) of which occurred during cardiopulmonary bypass or some

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 01/04/2010 - 03/29/2010*
	FBI NUMBER 1828100

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mark A. Sutter, President and Chief Executive Officer

FIRM NAME Terumo Cardiovascular Systems Corporation	STREET ADDRESS 6200 Jackson Road
CITY, STATE, ZIP CODE, COUNTRY Ann Arbor, MI 48103-9586	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

other procedure; examples of these seven failures include CR-14743 (received 7/1/2009, serial number 1071), CR-14085 (received 4/15/2009, serial number 1033), and CR-13471 (received 1/30/2009, serial number 1043).

- ii. EOA or EO8 error codes (heater failure): Your firm received ten (10) complaints of heater failures for your HX2 device, six (6) of which occurred during a cardiopulmonary bypass procedure or during priming for bypass; examples of these five failures include CR-12694 (received 10/16/2008), CR-13784 (received 3/9/2009), and CR-15747 (received 10/19/2009).

Each of these types of failures result in failure of a single channel of the HX2 leaving the channel inoperable. For each of these 13 complaints your firm failed to collect and document complaint/event information, to include patient follow-up questions or relevant clinical information, to determine if the failures resulted in a serious injury or device malfunction. According to procedure (b) (4) titled "Complaint Reporting" for all complaints that occurred during prime, cardiopulmonary bypass, vein harvesting, or during other procedure your firm is to (b) (4)

(b) (4)

Additionally, your firm failed to gather patient follow-up information for complaint CR-15554 (received 9/25/2009) which occurred during the priming of the system prior to bypass. Similarly, for complaint number CR-14582 (received 6/12/2009) the question "Was the surgery completed successfully" is answered as "unknown", yet the complaint documents no serious injury or death occurred. No complaint/event information, to include patient follow-up questions or relevant clinical information was documented for complaint CR-14582.

Part B of this observation are repeat observations from the 2004 FDA Warning Letter 2004-DT-06 and the 2008 FDA 483, Observation 10.

OBSERVATION 8

Quality system procedures were not established.

Specifically, your firm's procedure (b) (4) titled (b) (4) (rev. (b) (4) released 8/17/2009) documents your firm's procedures for the Engineering/Medical Risk (EMR) team and Quality Board which evaluate "current or potential issues regarding Terumo CVS products pertaining to patient safety, liability, regulatory compliance, and recall." Section 6.3 of this procedure documents that (b) (4)

(b) (4) Your firm's Plant Manager stated an EMR report and HHE are the two documents that the Quality Board will use to make determinations on possible regulatory action related to potential health risk issues. However, your firm has not established a procedure on when an HHE is required, who is responsible and qualified to address the requirements of the HHE, and how the HHE is to be conducted. For example:

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A. On or about 8/19/2009, your firm convened a Quality Board (QB) regarding the HX2 Temperature Management System (HX2) mixing valve failures seen in the field. As a result the health hazard evaluation (b) (4) was created. Completing this HHE form requires determining how many devices from affected lots are expected to develop the defect. However, the failure occurrence rate calculated looks at the failure of a component which is half the rate of failure of the device as a whole. This calculation looks at the rate of known failures but does not predict the failure of the affected lots. The same HHE later states "(b) (4)"

(b) (4)
(b) (4)

The hazard analysis for the HX2 lists the severity of a backup system/channel connected incorrectly, which could lead to patient injury, as a (b) (4) and identifies the potential harms as "(b) (4)"; the (b) (4)

(b) (4)
(b) (4)
(b) (4)
(b) (4)

. However, the HHE also states "(b) (4)"

As of the date of HHE (b) (4) (8/19/2009) your firm had manufactured and distributed approximately (b) (4) HX2 Temperature Management Systems.

B. Health hazard evaluation (b) (4) regarding inaccuracies involving the CDI 500 Blood Parameter Monitoring System device manufactured and distributed by your firm is not written to represent all potential adverse health outcomes to the patient. Review of the CDI 500 hazard analysis, dated March 3, 2009 lists unwarranted intervention to adjust the patient's pH, CO₂, O₂, potassium, Hct/Hgb and/or O₂ saturation due to inaccurate information provided by the device as "(b) (4)"

(b) (4); but the assessment of hazards associated with the use of defective product is marked as "no adverse health consequences" in (b) (4)

MEDICAL DEVICE REPORTING (MDR)

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OBSERVATION 9

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, medical device reports (MDR) were not submitted to FDA in the following instances:

- A. Complaint CR-10528 was received on 1/24/2008 regarding a falsely elevated potassium measurement with the CDI500 monitor serial number 1607 and CDI510H disposable sensor with lot 2008-06AK with K+ code 68A. The inaccuracy occurred during a cardiopulmonary bypass procedure. The cardiopulmonary bypass team erroneously took actions to lower the patient's potassium level, including the administration of furosemide. The CDI500 serial number 1607 and CDI510H sensor with lot 2008-06AK with K+ code 68A was measuring 9.5mM of potassium during a portion of a cardiopulmonary bypass procedure. A blood gas analysis by independent means was performed during the bypass procedure to verify the accuracy of the measurement of 9.5mM. Blood gas analysis confirmed the patient's potassium level to be 5.5mM. A medical device report was not submitted to FDA regarding this event.

Additionally, the Quality Board team at Terumo Cardiovascular Systems in Ann Arbor, Michigan met on/about 6/5/2009 regarding potassium inaccuracies with the CDI500 and CDI510H and the potential need for regulatory action. Complaint CR-10528 was referenced during this Quality Board meeting. A medical device report was not submitted after review of CR-10528 in Ann Arbor at the Quality Board meeting.

- B. Complaint CR-16046 was received on 11/19/2009 alleging the CDI 500 AHCT Blood Parameter Monitoring System, serial number 3028, turned itself on and off four (4) times during a cardiopulmonary bypass procedure. A medical device report was not submitted regarding this event.

- C. Between the dates of 4/1/2008 - 12/2/2009 your firm received the following complaints related to the HX2 Temperature Management System (HX2):

- i. Twenty-three (23) complaints regarding EOE and EOD error codes for the HX2 Temperature Management System (HX2). Sixteen (16) of these 23 complaints were reviewed; seven (7) of these sixteen (16) complaints recorded that the equipment failed during bypass surgery or some other procedure. Additionally, complaint CR-14582 documents that a patient injury is "unknown". Medical device reports were not submitted to FDA regarding these device failures. Examples of these complaints include CR-13325, CR-14085, and CR-16254. The IFU for the HX2 documents EOE and EOD errors require either switching channels or using backup equipment. Health Hazard Evaluation (b) (4) documents risks of this failure including delaying the procedure and thereby lengthening the time on cardiopulmonary

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bypass. Medical device reports were not submitted for any of these complaints.

- ii. Fourteen (14) complaints regarding EO8 and EOA error codes for the HX2 Temperature Management System which makes the failed channel unusable and requires the perfusionist to either switch equipment or change channels. Thirteen (13) of these fourteen (14) complaints were reviewed; six (6) of these thirteen complaints occurred during bypass surgery or during priming for bypass. Medical device reports were not submitted to FDA regarding these device failures. Examples of these complaints include CR-12484, CR-14840, and CR-15747. The instructions for use (IFU) for the HX2 documents EO8 and EOA errors require either switching channels or using backup equipment. Medical device reports were not submitted for any of these complaints.

D. On 11/9/2009, your firm received complaint CR-15947 in which your customer contacted your firm stating a patient died in which one of your firm's cannula products (21 Fr. Soft Flow Extended Arterial cannula; part number 4948; lot number 0556925) was used during the cardiopulmonary bypass procedure. During the procedure a clot was found "entangled in the diffuser tip of the cannula upon removal from the patient." The investigation conducted by your firm did not determine if your firm's product caused or contributed to the patient's death. No MDR was filed with FDA for this complaint; your firm determined this complaint was not reportable. (Refer to Observation 2C)

E. Your firm has received at least three (3) separate complaints (PPR 402, PPR 392, and PPR 92) where your firm's VirtuoSaph (Endoscopic Vein Harvesting System) failed during a cardiopulmonary bypass operation. In each of these three events the surgeon reported to your firm they needed to switch to an "open leg technique" which means the surgeon had to surgically cut open the patient's leg to retrieve the vein used for bypass instead of by endoscopic means. In each of these three separate complaints your firm did not file a medical device report (MDR) to FDA.

Failing to issue MDR for these complaints is a repeat observation from the 2006 FDA Warning Letter 2006-DT-27.

OBSERVATION 10

An individual medical device manufacturer report submitted per FDA Form 3500A did not contain in Block B a description of the event or problem to include a discussion of how the device was involved and the nature of the problem.

Specifically, the MEDWATCH FORM FDA 3500 (#18288100-2008-00296 of 6/5/08) does not contain in its Block B "ADVERSE EVENT OR PRODUCT PROBLEM" the description as provided in the original customer complaint # CR-11423 of 5/14/08 which claims the pump model #801040, "failed during bypass surgery".

The MDR Block B.5. states only, "During routine testing and maintenance, the roller pump displayed a "motor error" message. There was no adverse consequence to a patient as a result of this event."

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While the complaint explains the pump failed during bypass surgery, the MDR states that the failure occurred during routine testing.

This is a repeat observation from the 8/11/2008 FDA 483; Observation 11.

OBSERVATION 11

A supplemental report was not submitted to FDA within one month following receipt of information that was not provided when the initial report was submitted.

Specifically, on 04/06/2008, your firm completed the investigation of the failure of an Air Bubble Detection (ABD) Ultrasonic Air Sensor (UAS) that was used during a cardiopulmonary bypass procedure (Complaint Document # CR-10025 of 11/27/2007). On 01/07/2010, approximately 21 months later, your firm submitted to FDA this information supplemental to MDR #1828100-2007-00472.

PURCHASING CONTROLS

OBSERVATION 12

Adequate quality requirements that must be met by suppliers were not established.

Specifically:

- A. Your firm has not ensured that your firm's sole supplier of Air Bubble Detection (ABD) Ultrasonic Air Sensor (UAS) devices provides your firm with ABD UAS devices that conform to specifications. Following your firm's 2007-2008 domestic and international recall (Z-530/532-2008) of more than (b) (4) ABD UAS devices for nonconformities including false air emboli detection alarms, the inability to reset ABD systems, and causing arterial pumps to stop during bypass surgery, this supplier's replacement ABD UAS devices continued to exhibit these same nonconformities. For example:
 - i. On 03/28/2008, your firm received complaint CR-11052, involving ABD UAS, part # 5773, serial # 10496, and reporting, "Air sensor alarms and shuts off the pump even when there's plenty of fluid and no air in the system." Your firm documented that "SN 10496 belongs to a new ABD sensor sent out as a recall replacement."
 - ii. Between 04/22/2009 and 11/11/2009, your firm received three (3) complaints, CR-15968, CR-15904, and

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CR-14129, involving three (3) recall replacement ABD UAS devices, and alleging failures in the field including continuous ABD system alarming with no air present (alleged false alarms) and/or the inability to reset ABD systems. Your firm identified these ABD UAS devices as defective, and included supplier workmanship as a root cause for these confirmed device failures.

iii. Nonconformance Reports, NCR # 6248, Rev. ^{(b) (4)} of 07/16/2009, and NCR # 6850, Rev. ^{(b) (4)} of 12/18/2009, document that ABD UAS, part # 149673, serial # 12420, manufactured on 05/08/2009, failed your firm's incoming functional testing after receipt both on 07/01/2009 and again on 11/03/2009. On both occasions, these device failures produced in your firm's ABD UAS test set-up false air bubble detection alarms and the inability to reset your firm's heart-lung device, model 8000, safety monitor. Following the first device failure, your firm returned the failed part to this supplier "for evaluation and it was found to have no defects, root cause unknown, unit was retested without failure." Your firm attributed both device failures to supplier workmanship.

B. Your firm currently receives ^{(b) (4)} different printed circuit boards (PCB) from a single supplier. Since 1/1/2008 your firm has received approximately ^{(b) (4)} PCBs from this supplier. These boards go into a large majority of your products including, but not limited to: 4" and 6" roller pumps, HX2, ABD, CDI-500, and pressure boards. However, your firm has not adequately evaluated this supplier to ensure it can provide these ^{(b) (4)} PCBs according to specifications and overall workmanship quality. For example, from 8/13/2009 to 2/1/2010 your firm has generated at least 11 nonconformance reports (NCR) regarding loose/insufficient solder, flux corrosion, and other workmanship failures from PCBs manufactured by this supplier. Examples include NCR 6993 (received 2/2010), NCR 6972 (received 1/27/2010), NCR 6634 (received 10/22/2009), and NCR 6433 (received 8/31/2009). Each of these four NCRs reference risk assessment ^{(b) (4)} which was initially created in 5/2006 and documents the ^{(b) (4)}. Additionally, on or about 1/12/2009 your firm concluded it would no longer issue Supplier Corrective Action Reports (SCAR) to this same PCB supplier. Your firm continues to receive PCBs from this supplier and created CA 154 and PA 155 on 7/2006 to address known workmanship issues with this same supplier. To date these corrections have not been implemented (refer to Observation 2B).

Additionally, from 11/2007 to 3/18/2010 your firm has documented at least 101 complaints from your service department where the ^{(b) (4)} board (a PCB used in the CDI-500 and manufactured by the same supplier mentioned here) needed to be replaced due to failures seen in the field by customers. Eleven (11) of these more recent 101 complaints were reviewed and found ^{(b) (4)} printed circuit boards were determined to have failed and were replaced by your firm. Your supplier has not been made aware of these failures; as of 3/18/2010 your firm continues to receive PCBs from this supplier. For example, complaints CR-15218, CR-14627, CR-14399 and CR-15708 were received by your firm for CDI-500 field failures which your firm later determined to be related to failure of the ^{(b) (4)} printed circuit board. Each of the related complaint investigations state that due to the low risk of the complaint no further investigation will be performed to determine the cause of the ^{(b) (4)} failure and no further action is required.

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PRODUCTION AND PROCESS CONTROLS

OBSERVATION 13

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated and approved according to established procedures.

Specifically, the following process validations were not adequately validated:

- A. The (b) (4) used to coat various models of (b) (4) and Poly(2-methoxyethylacrylate) coating is not fully validated. According to manufacturing procedure (b) (4) (b) (4) document no. (b) (4) (b) (4) and (b) (4) (b) (4). The process validation (b) (4) (b) (4) included (b) (4) (b) (4) validation does not address (b) (4) (b) (4).
- B. Your firm created corrective action 33 to address corrections to the air bubble detector (ABD) regarding oversensitivity failures. Part of this corrective action included an update to the finished device test procedure used by your supplier of the ABD. The updates to this test required validation activities to take place, which occurred on or around 8/25/2006 according to your supplier's document number (b) (4) titled (b) (4) (b) (4). (b) (4) documents the qualification requirements of the validation along with the validation parameters. This supplier validation was not approved by your firm prior to the supplier conducting the validation.

However, your firm's Senior Product Development Engineer provided documentation which states that (b) (4) (b) (4). These factors were not documented in your supplier's validation study (b) (4) (b) (4). Additionally, your supplier now conducts this sensitivity (b) (4) to each ABD device prior to its final release; however, this was not required or performed under the validation study documented in (b) (4) (b) (4). Additionally, your firm provided the test results of the validation study your supplier conducted regarding the oversensitivity of the ABD. This validation was only conducted by a (b) (4) (b) (4). The air bubble used by your supplier to conduct this validation (and subsequent 100% finished product inspection) uses a (b) (4) (b) (4). No documentation was provided which documents the variation in the bubble size created (b) (4) (b) (4).

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(b) (4)

OBSERVATION 14

Rework of nonconforming product did not include complete retesting and reevaluation to ensure that the reworked product met current approved specifications.

Specifically, your firm's APS-1 4" Roller Pump s/n 4076 was released and shipped without record of the **(b) (4)** **(b) (4)** in required by SOP # **(b) (4)**

Routine production and testing of the APS-1 4" Roller Pump s/n 4076 on 2/20/08 found error messages and motor stop during functional testing after routine burn-in. This pump was then reworked and released on 3/17/08 (per NCR #4061) without record of the additional 4 hour post rework-burn in required by SOP # **(b) (4)**. After this 3/17/08 rework this same pump was subject of customer complaint #CR-11504 of 5/22/08 alleging malfunction. Upon return evaluation of this pump, the root cause was found to be "failure of the Drive Motor".

DESIGN CONTROLS

OBSERVATION 15

The design was not validated using production units or their equivalents.

Specifically, the design validation of your firm's **(b) (4)** (Project **(b) (4)**, an integrated hardware and software device used for control of your firm's heart-lung devices, model APS1 (including control of the Air Bubble Detection (ABD) system on the APS1), was performed using ABD Ultrasonic Air Sensor (UAS) devices that had already been recalled by your firm. According to "**(b) (4)** Protocol # **(b) (4)** Version **(b) (4)** (Project **(b) (4)**, Revision **(b) (4)** Review and Approval," dated 10/30/2007, your firm's Project **(b) (4)** design validation included nine (9) of eleven (11) simulated perfusion cases performed on APS1 test set-up units installed with recalled ABD UAS devices (ABD UAS part # 5773, serial # 2355 and 3786). To simulate perfusion during heart-lung bypass surgical procedures, your firm conducted these nine (9) cases between 10/31/2007 and 11/07/2007 on the following five (5) APS1 test set-up units: child; small adult; loss of arterial pump, use of backup arterial pump; large adult; and Capiiox. These specific ABD UAS devices (part # 5773, serial # 2355 and 3786) used for these nine (9) simulated perfusion cases were included in your firm's 2007-2008 recall of ABD UAS devices, which was reported by your firm to FDA on 06/14/2007 (Z-530/532-2008) for nonconformities including false air emboli detection alarms, the inability to reset ABD systems, and causing arterial pumps to stop during bypass surgery.

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FIRM NAME Terumo Cardiovascular Systems Corporation	STREET ADDRESS 6200 Jackson Road
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CITY, STATE, ZIP CODE, COUNTRY Ann Arbor, MI 48103-9586	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer
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Observation Annotations

Observation 1: Promised to correct.	Observation 2: Promised to correct.
Observation 3: Promised to correct.	Observation 4: Promised to correct.
Observation 5: Promised to correct.	Observation 6: Promised to correct.
Observation 7: Promised to correct.	Observation 8: Promised to correct.
Observation 9: Promised to correct.	Observation 10: Promised to correct.
Observation 11: Promised to correct.	Observation 12: Promised to correct.
Observation 13: Promised to correct.	Observation 14: Promised to correct.
Observation 15: Promised to correct.	

*** DATES OF INSPECTION:**

01/04/2010(Mon), 01/05/2010(Tue), 01/06/2010(Wed), 01/07/2010(Thu), 01/08/2010(Fri), 01/11/2010(Mon), 01/12/2010(Tue), 01/13/2010(Wed), 01/14/2010(Thu), 01/15/2010(Fri), 01/25/2010(Mon), 01/26/2010(Tue), 01/27/2010(Wed), 01/28/2010(Thu), 01/29/2010(Fri), 02/01/2010(Mon), 02/02/2010(Tue), 02/03/2010(Wed), 02/04/2010(Thu), 02/05/2010(Fri), 02/11/2010(Thu), 02/12/2010(Fri), 02/16/2010(Tue), 02/17/2010(Wed), 02/18/2010(Thu), 02/19/2010(Fri), 02/22/2010(Mon), 02/23/2010(Tue), 02/24/2010(Wed), 02/25/2010(Thu), 02/26/2010(Fri), 03/05/2010(Fri), 03/12/2010(Fri), 03/17/2010(Wed), 03/18/2010(Thu), 03/29/2010(Mon)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ryan J. Benedict, Investigator <i>Ryan J. Benedict</i> Charles M. Spyr, Investigator <i>Charles M. Spyr</i> Kimberly Lewandowski-Walker, Investigator <i>Kimberly Lewandowski-Walker</i> Gary D. Urbiel Goldner, Investigator <i>Gary D. Urbiel Goldner</i>	DATE ISSUED 03/29/2010
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