Class 2 Device Recall CDI 500 Blood Parameter Monitoring System

Class 2 Device Recall CDI 500 Blood Parameter Monitoring System

See Related Information[22]

Date Initiated by Firm	August 07, 2015
Date Posted	September 09, 2015
Recall Status[1]	Terminated [3] on May 31, 2016
Recall Number	Z-2742-2015
Recall Event ID	71937[23]
510(K)Number	K133658[24]
Product Classification	Monitor, blood-gas, on-line, cardiopulmonary bypass[25] - **Product Code** DRY[26]
Product	CDI 500 Blood Parameter Monitoring System. Provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature.
Code Information	500A, 500AHCT, 500AV, 500AVHCT CDI Blood Parameter Monitoring System 500; software version 1.69.
Recalling Firm/ Manufacturer	Terumo Cardiovascular Systems Corporation 6200 Jackson Rd Ann Arbor MI 48103-9586
For Additional Information Contact	Mary Swift 734-741-6173
Manufacturer Reason for Recall	Inaccuracies in SvO2, temperature, pH, pCO2, pO2, Hematocrit, and Potassium readings following a software upgrade to version 1.69.
FDA Determined Cause [2]	Software design
Action	A voluntary Urgent Medical Device Correction notice that clearly explains initial in-vivo calibration requirements, device operating ranges, and temperature measurements was sent on 08/17/2015, via express mail to consignees of CDI System 500 v1.69. Following the initial notice, Terumo will be updating the Operators Manual and will send the new manual to each consignee when available. One manual per unit at each facility will be provided. Customers with questions and return response forms may contact:

	Terumo Recall Email: tcvs.recall@terumomedical.com Terumo Recall Fax: 734-741-6149 Terumo CVS Customer Service: 1.800.521.2818, Monday - Friday, 8 a.m. □ 6 p.m. ET.
Quantity in Commerce	4638
Distribution	Worldwide Distribution-US (nationwide) including DC and PR and the states of AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, WA, WI, WV, and the countries of Australia, Belgium, Canada, Chile, Colombia, Hong Kong, Indonesia, Japan, Malaysia, Mexico, Philippines, Singapore, South Korea, Taiwan, Thailand, United Arab Emirates.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29].

510(K) Database	510(K)s with Product Code = DRY and Original Applicant = TERUMO CARDIOVASCULAR SYSTEMS CORP.[30]

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12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=71937
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K133658
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DRY
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DRY
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DRY
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
30. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DRY&knumber=&applicant=TERUMO%20CARDIOVASCULAR%20SYSTEMS%20CORP%2E

Page Last Updated: 08/26/2020

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19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=71937
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K133658
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