جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز داعم
Advance: Per'fusion System Platform (APS)

الجهاز المعني بالتابعه:

- Advanced Perfusion System Platform (APS)
- Trade Mark: Terumo Cardiovascular Systems Corporation
- Local Representative:

FDA بناء على التقرير الصادر عن وكالة ال
الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمل الجهاز، نرجو منكم
تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربط:
- التقرير الصادر عن وكالة ال

بلاغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- الملفوفات

مدير عام الصحة

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fac: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb
Class 2 Recall
220/240V AC, Advanced Perfusion System Platform (APS)

Date Posted
November 27, 2012

Recall Number
Z-0436-2013

Product
220/240V AC, Advanced Perfusion System Platform (APS) The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours on the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

Code Information
Catalog number: 801764 and all serial numbers

Recalling Firm/Manufacturer:
Terumo Cardiovascular Systems Corporation
6200 Jackson Road
Ann Arbor, Michigan 48103-9586

Reason for Recall
Terumo Cardiovascular System (TCVS) has received reports of a situation where users experienced a total loss of functionality for some System 1 units. The reports indicate that the units went blank and shut down with no sign of power and battery backup did not initiate. The result is all pumps stop, with no safety system functionality, and the battery would not be activated. The user would be

Action
Terumo Cardiovascular Systems sent a Urgent Medical Device Recall Correction letter dated November 14, 2012, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Terumo CVS is alerting all users of Terumo System 1 of the reports of malfunction. Customers were instructed to: 1. Review this Medical Device Safety Advisory. 2. Ensure that all users are aware of this notice. 3. Confirm receipt of this communication by faxing, or emailing the attached Customer Response Form to the fax number/email address indicated on the form. We encourage you to contact us with any questions or concerns: Terumo CVS

Quantity in Commerce
1647 total units

Distribution
Worldwide Distribution—USA (nationwide) including the states of AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NJ, NM, NV, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, VT, WA, WI, and WV.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ./cPDMN/pmnm.cfm
8. ./cfRL/cf.cfm
9. ./cfMAUDFTextSearch.cfm
10. ./cfRES/res.cfm
11. ./cfPMA/pma.cfm
12. ./cfPCD/classification.cfm
13. ./cfStandards/search.cfm
14. ./cfCFR/CFRSearch.cfm
15. ./cfPCD_RH/classification.cfm