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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٢٥
رقم الصادر: ١٢/١/٥٨٦
بيروت، في: ٥ - كانون الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز دلبي
Advanced Perfusion System Platform (APS)

الجهاز المعني بالمتابعة:

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

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

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
قلم السجل
وزارة الصحة العامة

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

Class 2 Recall
220/240V AC, Advanced Perfusion System Platform (APS)

See Related Information [20]

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. Assure 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 Customer Service 1-800-521-2818, Recall Fax 1-734-741-6149 Customer Service Hours: Monday thru Friday, 8 AM - 6 PM ET.
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, IA, 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.

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