



رقم المحفوظات: ٤٨/٤٥
رقم الصادر: ١٤/٧/٢٥٢٢٩
بيروت، في: ٢١ تموز ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

GE Healthcare, Avance, Avance CS2, Aisys, Aespire View, and Engstrom.
Intended for volume or pressure control ventilation

الجهاز المعنى بالمتابعة:

- GE Healthcare, Avance, Avance CS2, Aisys, Aespire View, and Engstrom. Intended for volume or pressure control ventilation.
- Trade Mark: GE Healthcare, LLC
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

والذي يشير الى وجود خلل في عمل الصنف المذكور أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

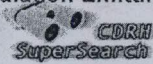
- ✓ دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار



FDA Home³ Medical Devices⁴ Databases⁵

Medical & Radiation Emitting Device Recalls

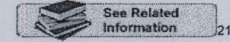


510(K)⁷ | Registration & Listing⁹ | Adverse Events⁹ | Recalls¹⁰ | PMA¹¹ | Classification¹² | Standards¹³ | Inspections¹⁴ | CFR Title 21¹⁵ | Radiation-Emitting Products¹⁶ | X-Ray Assembler¹⁷ | Medsun Reports¹⁸ | CLIA¹⁹ | TPLC²⁰

New Search

Back to Search Results

Class 1 Recall
GE Healthcare, Avance, Avance CS2,
Aisys, Aespire View, and Engstrom



Date Classified October 15, 2013

Recall Number Z-0010-2014

Product GE Healthcare, Avance, Avance CS2, Aisys, Aespire View, and Engstrom. Intended for volume or pressure control ventilation.

Code Information

Mfg Lot or Serial # APHS00701 APHS00802 APHS00729 APHS00730 APHS00700 APHS00692
 APHS00932 APHS00886 APHS00861 APHS00865 APHS00866 APHS00867 APHS00868
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Recalling Firm/ Manufacturer	GE Healthcare, LLC 3000 N Grandview Blvd Waukesha, Wisconsin 53188-1615
Manufacturer Reason for Recall	GE Healthcare has recently become aware of a potential safety issue involving unresponsive buttons on the display of the Engström ventilator and the Aespire View, Aisys, and Avance anesthesia machines. As a result of a manufacturing issue, the buttons on the left, right, and bottom keypads may not always detect button presses. This may result in the inability to access certain menu functions wh
Action	Consignees were sent on 8/28/2013 a GE Healthcare "Urgent Medical device Correction" letter dated August 28, 2013. The letter was addressed to Chief of Anesthesia, Health Care Administrator / Risk Manger and director of Biomedical / clinical engineering. The letter described the Safety Issue, Safely Instructions, Affected Product Details, Product Correction and Contact Information (1-800-345-2700 US).
Quantity in Commerce	911 (252 US, 659 OUS)
Distribution	Worldwide Distribution-USA (nationwide) including the states of US: AK, AZ, CA, CO, DE, FL, GA, IL, KY, LA, MD, MI, MN, MS, MT, NV, NY, NC, OH, OR, PA, SC, TX, WY, and VI and the countries of AUSTRALIA, AUSTRIA, BANGLADESH, BELGIUM, BOLIVIA, BRAZIL, CANADA, CHILE, CHINA, COST ARICA, CROATIA, CZECH REPUBLIC, EGYPT, FINLAND, FRANCE, GERMANY, GREECE, INDIA, INDONESIA, IRAQ, ITALY, JAPAN, KAZAHHSTAN, REPUBLIC OF KOREA, KUWAIT, LEBANON, LITHUANIA, MAURITITUS, MEXICO, MOROCCO, NETHERLANDS, NEW ZEALAND, NIGERIA, PAKISTAN, PERU, PHILIPPINES, POLAND, RUSSIAN FEDERATION, SAUDI ARABIA, SOUTH AFRICA, SPAIN, SWEDEN, SWITZERLAND, TAIWAN, THAILAND, TURKEY, UNITED ARAB EMIRATES, UNITED KINGDOM, VIETNAM, and VENEZUELA.

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