



رقم المحفوظات: ٢٧/٢٥
رقم الصادر: ١٣/١١٤٥٧٧
بيروت، في: ٢٧ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Giraffe OmniBed and Giraffe Incubator

الجهاز المعنى بالمتابعة:

- Giraffe OmniBed and Giraffe Incubator p/n 6600-0723-700 (rev A and B)
- Trade Mark: GE Healthcare
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA
والذي يشير الى وجود خلل في عمل الصنف المذكور اعلاه 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

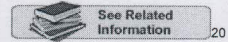
د. وليد عمار



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Class 1 Recall
Giraffe Omnibed and Incubator



Date Posted April 05, 2013

Recall Number Z-1051-2013

Product Giraffe OmniBed® and Giraffe Incubator p/n 6600-0723-700 (rev A and B) labeled in part: ***GE Healthcare 8880 Gorman Road Laurel, MD 20723 U.S.A. www.gehealthcare.com***. GE Healthcare Giraffe Omnibed is a combination of an infant incubator and an infant warmer.

Code Information OmniBed Serial Numbers: HDGR52546, HDGR52736, HDGR52802, HDGR52861, HDGR52910, HDGR52958, HDGR53007, HDGR53058, HDGR53110, HDGR53185, HDGR52547, HDGR52737, HDGR52803, HDGR52862, HDGR52911, HDGR52959, HDGR53008, HDGR53059, HDGR53112, HDGR53186, HDGR52558, HDGR52739, HDGR52804, HDGR52863, HDGR52912, HDGR52960, HDGR53009, HDGR53060, HDGR53113, HDGR53187, HDGR52609, HDGR52740, HDGR52805, HDGR52864, HDGR52913, HDGR52961, HDGR53010, HDGR53061, HDGR53114, HDGR53188, HDGR52610, HDGR52741, HDGR52806, HDGR52865, HDGR52914, HDGR52962, HDGR53011, HDGR53062, HDGR53115, HDGR53189, HDGR52613, HDGR52742, HDGR52813, HDGR52866, HDGR52915, HDGR52963, HDGR53012, HDGR53063, HDGR53116, HDGR53190, HDGR52620, HDGR52743, HDGR52814, HDGR52867, HDGR52916, HDGR52964, HDGR53013, HDGR53064, HDGR53117, HDGR53191, HDGR52621, HDGR52744, HDGR52815, HDGR52868, HDGR52917, HDGR52965, HDGR53014, HDGR53065, HDGR53119, HDGR53192, HDGR52622, HDGR52745, HDGR52816, HDGR52869, HDGR52918, HDGR52966, HDGR53015, 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HDGR53005, HDGR53056, HDGR53108, HDGR53176, HDGR52735, HDGR52799, HDGR52860, HDGR52909, HDGR52957,

HDGR53006, HDGR53057, HDGR53109, and HDGR53181. ***Incubator Serial Numbers:
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 HDHR52703, HDHR52771, HDHR52876, HDHR52993, HDHR52704, HDHR52772, HDHR52877,
 HDHR52994, HDHR52707, HDHR52773, HDHR52880, and HDHR52995.

Recalling Firm/ Manufacturer	GE Healthcare, LLC 3000 N Grandview Blvd Waukesha, Wisconsin 53188-1615
For Additional Information Contact	James Giles 262-513-4122
Reason for Recall	Neonatal beds and incubator display boards may randomly overwrite stored information and radiant heater and oxygen set points upon power up or recovery from a power failure.
Action	GE Healthcare sent an "Urgent Medical Device Correction" letter, dated January 8, 2013. The letter identified the product, the problem, and the action to be taken by the customer. Customers were given the safety issue and instructions for continued use of the Giraffe OmniBed and Incubators, as well as given the affected product details. GE Healthcare will correct all affected Giraffe Incubators and Giraffe OmniBeds at no cost, and will contact customers to arrange for this correction. If customers have any questions or concerns regarding this notification, please call: United States: 1-800-345-2700. For other countries, please contact your local GE Healthcare Service Representative.
Quantity in Commerce	679 units
Distribution	Worldwide Distribution -- USA in the states of AR ,CA, CO, DC, FL, GA, HI, ID, IL, IN, KS, MA, MD, MI, MO, MS, NC, NE, NJ, NY, NV, OH, PA, TN, TX, VA, WA, WI, and WV, and the countries of Arab Emirates, Albania, Australia, Belgium, Brazil, Canada, Chile, China, Croatia, Czech., Denmark, Ecuador, Estonia, Finland, France, Germany, Hungary, Italy ,Korea, Kurdistan, Lebanon, Macedonia, Malaysia, Mexico, Norway, Oman, Poland, Russia, San Salvador, Saudi Arabia, Singapore, South Africa, Sweden, Turkey, Uruguay, Venezuela, and United Kingdom.

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