الموضوع: إشعار بمتابعة جهاز طبي مغروس

Newport HT70 and HT70 Plus Ventilator (HT70 Plus ventilator family)

الجهاز المعني بالمتاحة:
- Newport HT70 and HT70 Plus Ventilator (HT70 Plus ventilator family).
- Trade Mark: Newport Medical Instruments Inc.
- Local Representative:

FDA

بناء على التقرير الصادر عن وكالة ال
والتسويقية الصادرة عن الشركة المصنعة والتي تشير إلى وجود خلل في عمل الـ، السوارد

إعلاناً مما قد يؤثر على سلامة المريض، نرحب منكم تعميم هذه النشرة على جميع المستشفيات
المعنية.

مرفق ربطا:

FDA

التقرير الصادر عن وكالة ال

الدارة البرنامج والمشاريع
للسلطات الحكومية
المختصات
Medical & Radiation Emitting Device Recalls

Class I Recall
Newport Medical Instruments HT70 and HT70 Plus ventilator Power Pac batteries

Date Posted: April 26, 2013
Recall Number: Z-1717-2013

Product: Newport Medical Instruments HT70 and HT70 Plus ventilator Power Pac batteries.
Model number: HT70 and HT70 Plus. The HT70 and HT70 Plus ventilator systems are intended to provide continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation through invasive or non-invasive interfaces.

Code Information: Model number: HT70 and HT70 Plus Power Pac battery serial number range: 2069134110001 to 2080081320050, Rev. C through Rev. F.

Recalling Firm/Manufacturer: Newport Medical Instruments Inc
1620 Sunflower Ave
Costa Mesa, California 92626-1513

Reason for Recall: Newport Medical Instruments is conducting a voluntary recall of certain Newport Medical Instruments HT70 and HT70 Plus ventilator Power Pac batteries due to customer reports of HT70 and HT70 Plus ventilators alarming and going into internal backup battery sooner than expected while the ventilator is being operated on Power Pac battery.

Action: Newport Medical Instruments sent an Urgent Medical Device Recall letter dated April 4, 2013, via FedEx to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers who sold the affected product to another party, or placed the affected product with a patient or healthcare provider were instructed to immediately inform the other party, patient, or healthcare provider of this action and provide them with a copy of the letter. If customers were using the affected product, they should ensure that an alternate source of power is available nearby. Customers were also instructed to report any issues with Newport HT70 and HT70 Plus ventilators or Power Pac batteries to the Voluntary Product Recalls team.

Quantity in Commerce: 2528 ventilators and 1864 power pac batteries.

Distribution: Worldwide distribution - USA including AL, AR, AZ, CA, CO, CT, DE, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MT, NC, NH, NJ, NV, NY, OH, OK, OR, PA, Puerto Rico, RI, SC, TN, TX, UT, VA, WA, and WI. Internationally to Argentina, Australia, Bangladesh, Belgium, Bolivia, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Ecuador, Egypt, France, Greece, Hong Kong, Hungary, India, Indonesia, Israel, Italy, Japan, Kazakhstan, Kosovo, Lebanon, Lithuania, Malaysia, Mexico, Namibia, Nepal, Norway, Oman, Paraguay, Peru, Philippines, Poland, Qatar, Saudi Arabia, Singapore, South Africa, South Korea, Sri Lanka, Switzerland, Taiwan, Thailand, Turkey, United Arab Emirates, United Kingdom, Venezuela, and Vietnam.

Links on this page:
6. /scripts/cdrh/devicesatfda/index.cfm
7. /fcPDM/pmcfm
8. /fcR/ct.cfm
9. /fcSHADE/TextSearch.cfm
10. /fcRES/res.cfm
11. /fcPDM/qa.cfm
12. /fcPCD/classification.cfm
13. /fcStandards/search.cfm
14. /fcCFR/CFsSearch.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/res.cfm?id=117179
7/3/2013