



رقم المحفوظات: ٤٨/٢٥  
رقم الصادر: ١٣٨١/٢٥٩٤٧  
بيروت، في: ٥ - آب - ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

**الموضوع:** إشعار بمتابعة جهاز طبي مغروس

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

الجهاز المعني بالمتابعة:

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

بناء على التقرير الصادر عن وكالة ال FDA والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد اعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

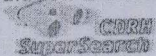
يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة العامة  
د. وليد عمار

[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

**Medical & Radiation Emitting Device Recalls**

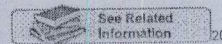


[510\(k\)](#)<sup>7</sup> [Registration & Listing](#)<sup>8</sup> [Adverse Events](#)<sup>9</sup> [Recalls](#)<sup>10</sup> [PMA](#)<sup>11</sup> [Classification](#)<sup>12</sup> [Standards](#)<sup>13</sup>  
[CFR Title 21](#)<sup>14</sup> [Radiation-Emitting Products](#)<sup>15</sup> [X-Ray Assembler](#)<sup>16</sup> [Medsun Reports](#)<sup>17</sup> [CLIA](#)<sup>18</sup> [TPLC](#)<sup>19</sup>

[New Search](#)

[Back to Search Results](#)

**Class 1 Recall**  
**Newport Medical Instruments HT70**  
**and HT70 Plus ventilator Power Pac**  
**batteries**



<b>Date Posted</b>	April 26, 2013
<b>Recall Number</b>	Z-1171-2013
<b>Product</b>	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 mechanical ventilatory support for the care of individuals who require mechanical ventilation through invasive or non-invasive interfaces
<b>Code Information</b>	Model number: HT70 and HT70 Plus Power Pac battery serial number range: 2096134110001 to 2292048120050, Rev. C through Rev. F
<b>Recalling Firm/Manufacturer</b>	Newport Medical Instruments Inc 1620 Sunflower Ave Costa Mesa, California 92626-1513
<b>Reason for Recall</b>	Newport Medical Instruments is conducting a voluntary recall on certain Newport Medical Instruments HT70 and HT70 Plus ventilator Power Pac batteries due to customer reports of Newport HT70 and HT70 Plus ventilators alarming and going to internal backup battery sooner than expected while the ventilator is being operated on Power Pac battery.
<b>Action</b>	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 instructed to report any issues with Newport <sup>®</sup> HT70 and HT70 Plus ventilators or Power Pac batteries to the Technical Support group to ensure proper device reporting procedures are followed. Please call 800-451-3111, extension 500, for U.S. customers; and 714-427-5811, extension 500 for international customers and you will be given further instructions). For questions regarding this recall call 714-427-5811, ext 344. A press release was issued by the firm on 04/18/13.
<b>Quantity in Commerce</b>	2528 ventilators and 1864 power pac batteries
<b>Distribution</b>	Worldwide Distribution - USA including US (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, 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, Ireland, 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 Viet Nam.

**Links on this page:**

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. [../cfPMN/pmn.cfm](..cfPMN/pmn.cfm)
8. [../cfRRL/ri.cfm](..cfRRL/ri.cfm)
9. [../cfMAUDE/TextSearch.cfm](..cfMAUDE/TextSearch.cfm)
10. [../cfRES/res.cfm](..cfRES/res.cfm)
11. [../cfPMA/pma.cfm](..cfPMA/pma.cfm)
12. [../cfPCD/classification.cfm](..cfPCD/classification.cfm)
13. [../cfStandards/search.cfm](..cfStandards/search.cfm)
14. [../cfCFR/CFRSearch.cfm](..cfCFR/CFRSearch.cfm)