



رقم المحفوظات: ٤٥/٨٨

رقم الصادر: ١٢/١/٢٠١٢

بيروت، في:

٥ - آب - ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Respironics V60 Ventilator

الجهاز المعنى بالمتابعة:

- Respironics V60 Ventilator
- Trade Mark: Respironics California 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  
أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات  
المعنية.

مرفق ربطاً:

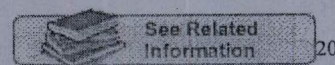
- التقرير الصادر عن وكالة ال FDA

يلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

د. وليد عمار  
مدير عام الصحة

**Class 1 Recall  
V60 Ventilator**



**Date Posted** June 17, 2013

**Recall Number** Z-1537-2013

**Product** Respironics V60 Ventilator, Model #V60  
Respironics Material P/N (Philips 12 Digit P/N): 85008 (85008) 1053613  
(989805628251) 1053614 (989805612101) 1053615 (989805613391)  
1053616  
(989805613661) 1053617 (989805611761) 1053618 (n/a) R1053618 (n/a)  
1076709 (n/a)  
1076715 (989805627411) 1076716 (989805627431) 1076717  
(989805627441) DU1053617  
(989805616411) U1053614 (989805636441) U1053617 (989805636631)  
Power Mgmt.  
Board, Respironics Material P/N: 1054358, Philips 12 Digit P/N:  
4536561512581.  
The V60 Ventilator is an assist Ventilator and is intended to augment patient breathing. It is intended for spontaneously breathing individuals who require mechanical ventilation: patients with respiratory failure, respiratory insufficiency, or obstructive sleep apnea in a hospital or other institutional settings under the direction of a physician. The V60 Ventilator is intended to support pediatric patients weighing 20kg (44 lbs.) or greater to adult patients. It is also intended for intubated patients meeting the same selection criteria as the noninvasive applications. It is intended to be used by qualified medical professionals, such as physicians, nurses, and respiratory therapists.

**Recalling Firm/  
Manufacturer** Respironics California Inc  
2271 Cosmos Ct  
Carlsbad, California 92011-1517

**Reason for  
Recall** Respironics California, Inc. has initiated a recall on the V60 ventilator because of an issue with the software on the V60 Power Management Board Assembly. If a component fails on the Power Management Board Assembly, it may cause ventilator support to be lost with potentially no audible alarm from the ventilator.

**Action** The firm, Philips Healthcare, sent a "MEDICAL DEVICE CORRECTION" letter dated June 3, 2013 to all customers who received the V60 Ventilators. The letter describes the product, problem identified and the actions to be taken. The customers were informed that the V60 ventilator may continue to be used in

accordance with its directions for use, pending the completion of the update. In addition, the customers were instructed to refer to their manual for additional information on warnings. A Philips Field Service Engineer, Approved Service Provider or Distributor will be contacting the customers to schedule a no-cost update and replacement of the Power Management Board Assembly Software on all V60 ventilators shipped from the manufacturer prior to April 1, 2013. If you need any further information or support concerning this issue, contact your local Philips Respiration representative at (800) 722-9377.

**Quantity in Commerce** 19,200 units total (12,060 units in US)