الجمهورية اللبنانية
وزارة الصحة العامة
الدكتور عام

رقم المخزونات: 08162
رقم الاصدار: 110178
بتاريخ: 6 آب 2012

جانب تقييم المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس 
Respironics V60 Ventilator

الجهاز المعني بالمتاحة:
- Respironics V60 Ventilator
- Trade Mark: Respironics California Inc.
- Local Representative:

بناءً على التقرير الصادر عن وكالة ال
وتوصية الصادرة عن الشركة المصنعة والتي تشير إلى وجود خلل في عمل الصفحات 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

Billy
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المخزونات

مدير عام الصحة
د. حسن عماد

Museum Street - Hussein Mansour Bldg - Beirut, Lebanon - Tel: 961 1615724, 915725 - Fax: 961 1615730 - Email: dirctgenrnl@mph.gov.lb
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 Respironics representative at (800) 722-9377.

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