Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: June 28, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Respironics California, Inc. Recall [Medical Device]

SUGGESTED ACTION: **Class I Recall; Approximately 19,200 Philips Respironics V60 Ventilators has been designated a Class I recall by the U.S. Food and Drug Administration (FDA); Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products were distributed in the State of Indiana. Respironics has notified all United States distributors, providers, sales personnel and customers that may have devices subject to this recall. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Respironics California, Inc. Recall of V60 Ventilator Designated Class I by FDA

Contact:
Consumer:
800-722-9377

Media:
Rachel Bloom-Baglin
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1-978-659-3748

FOR IMMEDIATE RELEASE - June 25, 2013 - Respironics California, Inc., a Philips Healthcare business, today announced that the company's worldwide recall of approximately 19,200 Philips Respironics V60 Ventilators has been designated a Class I recall by the U.S. Food and Drug Administration (FDA).

On June 4, Respironics initiated a voluntary recall to correct a software issue that may cause the V60 ventilator device to shut down. Following FDA review, Respironics was notified on June 17 of the Class I designation, as a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

The Philips Respironics 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, chronic respiratory insufficiency, or obstructive sleep apnea in a hospital or other institutional settings under the direction of a physician.

The recall was initiated to correct an issue with the V60 Ventilator Power Management (PM) Printed Circuit Board Assembly (PCBA) PlC software that was discovered through routine product monitoring. If the issue were to occur, there is a possibility that the V60 Ventilator could cease functioning during use, resulting in the loss of ventilator support, potentially with no audible alarm from the ventilator.

Respironics has notified all United States distributors, providers, sales personnel and customers that may have devices subject to this recall. The PM PCBA PIC software issue has been corrected, and Respironics will update the software on all V60 ventilators shipped from the manufacturer prior to April 1, 2013.

Customers who have questions about the recall or require further information or support concerning this issue, may contact their local Respironics representative via the Customer Care Center phone number: 800-722-9377, which is active 24/7. Any adverse events experienced with the use of this product should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch Web site at www.fda.gov/medwatch[1].

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