Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: February 19, 2014

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

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

SUBJECT: Respironics, Inc., a Philips Healthcare business - RECALL [Medical Device]

AFFECTED PRODUCT: **Philips Respironics Trilogy Ventilators**

SUMMARY: **Unclassified Recall; The recall is due a potentially defective component on the Trilogy Ventilator power management board, which could affect the function of the device. The recalled products include 600 Philips Respironics Trilogy Ventilators, comprising Trilogy Ventilator Models 100, 200 and 202.**

The recalled products were distributed throughout the United States. Philips Respironics has notified all United States distributors, providers, and customers that may have devices subject to this recall, and has provided affected device serial numbers for identification.

SUGGESTED ACTION: **For consumer inquiry only. Customers who have questions about the recall or require further information or support concerning this issue, may contact their local Philips Respironics representative via the Customer Care Center phone number: 1-800-345-6443, which is active 24/7.**

****

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.

Philips Respironics Initiates Recall of Trilogy Ventilator

Contact
Consumer:
1-800-345-6443

Media:
Mario Fante, mario.fante@philips.com
1-978-659-3572

Rachel Bloom-Baglin, Rachel.Bloom-Baglin@philips.com
978-659-3748

FOR IMMEDIATE RELEASE - February 19, 2014 - Murrysville, PA – Respironics, Inc., a Philips Healthcare business, today announced a worldwide recall of approximately 600 Philips Respironics Trilogy Ventilators, comprising Trilogy Ventilator Models 100, 200 and 202.

On February 11, 2014, Philips Respironics initiated a voluntary recall to address a potentially defective component on the Trilogy Ventilator power management board, which could affect the function of the device. If this issue is not corrected it is possible that the ventilator may fail to deliver mechanical breaths and that the alarm functionality may be reduced to indicate ventilatory failure, resulting in serious adverse health consequences or death. There have been no reports of death or serious injury related to this potential problem.

The Philips Respironics Trilogy Ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The devices are intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys.

During production testing Philips Respironics discovered that the Trilogy ventilators contain a potentially defective ferrite component on the power management board of the device. This recall affects 600 Trilogy Ventilator devices shipped between December 31, 2013, and January 30, 2014.

Philips Respironics is instructing customers to remove affected devices from service and to return them to Philips for replacement. All distributors, providers, and customers with potentially affected Trilogy devices will have their units replaced.

Philips Respironics has notified all United States and international distributors, providers, and customers that may have devices subject to this recall, and has provided affected device serial numbers for identification. Serial numbers of affected devices are located on the back of the device, as indicated in the accompanying product image.

Countries where affected devices have been shipped include the United States, France, United Kingdom, Hong Kong, India, Italy, Korea, Kuwait, Netherlands, and Singapore.

Customers who have questions about the recall or require further information or support concerning this issue, may contact their local Philips Respironics representative via the Customer Care Center phone number: 1-800-345-6443, which is active 24/7.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Philips Respironics Initiates Recall of Trilogy Ventilator
Photo