U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Respironics California, Esprit V1000 and V200 Ventilators - Power Failure May Occur

Recall Class: Class I

Date Recall Initiated: September 17, 2014

Devices: Esprit V1000 and V200 Ventilators, Model V1000 and V200, Installed with 3rd Generation Power Supplies, and 3rd Generation Power Supply Repair Part Kits – **See complete listing of serial numbers (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=130205)**.

- Manufactured and Distributed from December 21, 2012 to July 9, 2014

Use: The Esprit V1000 and V200 ventilators provide constant or periodic breathing help for adults and children, including newborns. These devices are used in hospitals and other health care settings.

Recalling Firm:
Respironics California Inc. (a division of Philips Healthcare)
2271 Cosmos Ct.
Carlsbad, California 92011-1517

Reason for Recall:

The 3rd Generation Power Supplies are installed in Esprit V1000 and V200 Ventilators and are also sold as 3rd Generation Power Supply Repair Kits. A part in the 3rd Generation Power Supply may prevent the ventilator from using AC power (electricity from a wall socket) or may fail and prevent the ventilator from switching back to AC power after using battery power. Additionally, if a battery is not present or is used up, the ventilators will not work.

Failure of the power supply may cause the ventilator to shut off, which may result in too much carbon dioxide in a patient's blood, not enough oxygen in the blood, or death.

There have been no reports of death or serious injury related to this potential problem.

Public Contact: For additional information or support contact a Philips Respironics representative at 1-800-722-9377.

FDA District: Los Angeles District Office

More Information about this Recall:

A Philips field service engineer, trained service provider, or distributor will contact customers to schedule a replacement of the recalled 3rd Generation Power Supply with a 3.1 Power Supply on all Esprit V1000 and V200 ventilators, and all 3rd Generation Power Supply Repair Part Kits.

Philips Healthcare sent an URGENT- Field Safety Notice dated September 17, 2014 to all customers who purchased the Esprit V1000 and V200 Ventilators.

The letter recommends that customers and users take these actions:

- Until the ventilator is replaced, it can still be used according to the directions for use.
- If the power supply fails during use and the ventilator loses standard electrical current, a different ventilator must be used.
- Be aware of the warnings from the Esprit V1000 and V200 operator's manual. When lights and sound alarms occur, including a flashing red light when the battery is low, the patient must be supported by a different ventilator.

About Class I Recalls

Class I recalls are the most serious type of recall. They involve situations when it is likely that use of these devices will cause serious health problems or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX.