eVent Medical LS, 5i, or 7i Inspiration Ventilators May Shut Down without Alarm

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Device

- All models of eVent Medical LS, 5i and 7i Inspiration ventilators manufactured prior to January 21, 2015
- Distribution Dates: February 14, 2013 to December 31, 2014
- Devices Recalled in the U.S.: 251 Units Nationwide

Device Use

The Inspiration LS, 5i and 7i ventilator systems provide constant breathing support for infants and adults. The ventilator is used in hospitals or health care facilities.

Inspiration 5i Ventilator

Reason for Recall

eVent Medical is recalling the LS, 5i, or 7i Inspiration ventilators because a faulty

switch on the ventilators' power board may fail, causing the ventilator to shut down without sounding an alarm. If the ventilator shuts down, the patient may not receive enough oxygen and could suffer serious adverse health consequences, including injury or death.

The company has received one report of this issue occurring, with no injuries and no deaths.

Who may be affected

- Health care providers using eVent Inspiration LS, 5i and 7i ventilators
- All patient groups who may be using these ventilator systems for breathing support.

What to Do

The firm sent an urgent field safety notice to all customers on October 13, 2015 informing them of this issue. The letter advised customers to immediately discontinue use of the affected ventilators until corrective actions could be taken.

To mitigate the risk of ventilator failure, the firm attached the instructions for removing the potentially faulty component from the power board.

Contact Information

Customers with questions are instructed to call eVent customer service: (949) 900-1917

Date Recall Initiated

October 13, 2015

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX

Additional Resources

- Class 1 Recall Inspiration Ventilator System

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Contact FDA