Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, December 07, 2015 3:57 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Inspiration LS, 5i and 7i Ventilator Systems by eVent Medical: Class I Recall - May Shut Down without Alarm

ISSUE: 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.

This recall includes 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

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

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

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

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

[12/07/2015 - Recall Notice - FDA]