Class I Medical Device Recall: CareFusion EnVe Ventilators (Distributed 12/2010 - 05/2012)

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: June 19, 2012

Product: EnVe Ventilators

The EnVe ventilators were manufactured from December, 2010 through January, 2012 and distributed from December, 2010 through May, 2012.

Use: The EnVe ventilator is intended for continuous breathing support for the care of newborns through adult patients who require mechanical ventilation. These ventilators are used in hospitals and other health care facilities.

Recalling Firm:
CareFusion, Inc.
3750 Torrey View Court
San Diego, California 92130

Reason for Recall: A leak may occur in the patient breathing circuit or the system, resulting in the ventilator not holding the set Positive End Expiratory Pressure (PEEP) value either intermittently or continuously. The device will activate both audible and visual alarms to notify the health care professional that ventilation delivery to the patient may be compromised. This product may cause serious adverse health consequences, including death.

Public Contact: Customers may contact CareFusion Customer Service at 1-800-554-8933.

FDA District: Minneapolis District Office

FDA Comments:

On June 19, 2012, the firm sent an "Urgent Product Recall" letter to their customers with a return receipt. The letter included the required action for the firm’s customers to take.

If ventilation resumes after an intermittent leak and the audible alarm stops, the firm directs users to clear the alarm indicator on the ventilator display by entering the Alarm Messages tab and pushing the alarm reset to clear the display. If the ventilator has a continuous leak and normal ventilation does not resume, the firm directs users to provide an alternate method of ventilation to the patient. The firm

instructs users to constantly monitor ventilator dependent patients to ensure that if a malfunction occurs, alternate ventilation can be provided.

The firm said it would contact its customers within 10 days to coordinate implementation of corrective action.

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences 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 [1] either online, by regular mail or by FAX.

Additional Links:

- Firm Recall Letter [2]

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http://www.mdtmag.com/news/2012/07/class-i-medical-device-recall-carefusion-enve-ventilators-distributed-12/2010-05/2012?qt-most_popular=0

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm
[2] http://www.carefusion.com/pdf/Alerts_and_Notices/EnVe/EnVe%20Customer%20Notification%20Letter.pdf