# CareFusion EnVe Ventilators: Class I Recall - Potential for Interruption of Patient Ventilation

U.S. Food & Drug Administration

**ISSUE**: FDA notified healthcare professionals of a Class I recall of all EnVe Ventilator model 19250-001, manufactured between December 2010 and May 2011, due to potential defects that can interrupt ventilation to the patient. The issues include: a potential delay in resuming ventilation after reconnection; a potential automatic reset; and a potential for disconnection during transport. Failure to adequately ventilate may lead to hypoxia or hypercarbia, which may result in serious neurological injury or death.

**BACKGROUND**: The CareFusion EnVe Ventilator is a portable ventilator used to provide breathing assistance to pediatric and adult patients in hospital and medical transport settings.

**RECOMMENDATION**: CareFusion is contacting facilities to coordinate hardware and software updates for affected ventilators.

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.htm [1]
- Download form [2] 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

[11/04/2011 - Recall Notice [3] - FDA]

SOURCE [4]

**Source URL (retrieved on *10/21/2014 - 11:20pm*):**
http://www.mdtmag.com/news/2011/11/carefusion-enve-ventilators-class-i-recall-potential-interruption-patient-ventilation

**Links:**
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm278634.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanM

edicalProducts/ucm278677.htm