



## Missouri Department of Health and Senior Services Advisory Alert

The Missouri Department of Health and Senior Services received the following news release regarding 128 EnVe™ ventilators.

### Carefusion Initiates Class I Recall Of EnVe Ventilators

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**FOR IMMEDIATE RELEASE** - October 19, 2011 - CareFusion (NYSE: CFN), a leading global medical device company, issued the following update regarding its recall of 128 EnVe™ ventilators affecting 29 customers. The FDA has classified this action as a Class I recall.

The voluntary recall only affects EnVe ventilators manufactured between December 2010 and May 2011 and therefore, has no affect on the company's current product production or shipping processes.

On September 12, the company sent an urgent Medical Device Recall Notification to customers stating the identified potential risks associated with the EnVe ventilators. The issues include: a potential delay in resuming ventilation after reconnection; a potential automatic reset; and a potential for disconnection upon transport. Failure to adequately ventilate may lead to hypoxia or hypercarbia, which may result in serious neurological injury or death. A Class I recall is defined as a reasonable probability of serious adverse health consequences or death associated with use of the defective units.

In the notification letter, customers were provided serial numbers of affected devices. This information is available at <http://www.carefusion.com/customer-support/alerts-notices/medical-device-recall-enve-ventilator.aspx><sup>1</sup>.

CareFusion is conducting a field corrective action to update the hardware and software on affected ventilators. The company had determined the root cause for each issue and is committed to updating each device in a timely manner with minimal disruption to our customers.

Instructions to customers

Customer inquiries related to this action should be addressed to CareFusion Technical Support at 800-554-8933.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program: by mail at MedWatch, HF-2, FDA 5600 Fishers

Lane, Rockville, MD 20852-9787; by phone at 1-800-332-1088; by fax at 1-800.FDA.0178 or at <sup>2</sup>[www.fda.gov/medwatch](http://www.fda.gov/medwatch)<sup>3</sup>.

#### About CareFusion

CareFusion (NYSE: CFN) is a global corporation serving the health care industry with products and services that help hospitals measurably improve the safety and quality of care. The company develops market-leading technologies including Alaris® infusion pumps, Pyxis® automated dispensing and patient identification systems, AVEA®, AirLife™ and LTV® series ventilation and respiratory products, Chloraprep® products, MedMined™ services for data mining surveillance, Nicolet™ neurological monitoring and diagnostic products, V. Mueller® surgical instruments, and an extensive line of products that support interventional medicine. CareFusion employs more than 14,000 people across its global operations. More information may be found at [www.carefusion.com](http://www.carefusion.com)<sup>4</sup>.

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