



## URGENT PRODUCT RECALL

Date: September, 2011

CareFusion 211, Inc.  
22745 Savi Ranch Parkway  
Yorba Linda, CA 92887, USA

Dear Valued Customer:  
Director of Biomedical Engineering  
Director of Respiratory Care  
Director of Risk Management

### **Product Name: AVEA® ventilator all models**

CareFusion has identified a potential risk associated with certain AVEA ventilators and affected replacement parts manufactured between March 1, 2009 and June 30, 2011. CareFusion is voluntarily initiating a field correction of the affected devices to preclude the possibility of this risk.

Serial Number: Please see enclosed

### **PROBLEM AND AFFECTED DEVICES**

**ISSUE:** Affected AVEA ventilators may develop a failure mode over time where the AVEA ventilator activates a false Extended High Ppeak alarm, opens the Safety Valve (by design) and stops ventilating. Despite activation of the Extended High Ppeak alarm the patient is not subjected to elevated airway pressures as a result of this issue.

**AFFECTED UNITS:** AVEA ventilator devices manufactured between March 1, 2009 and June 30, 2011, and AVEA ventilators which were serviced with affected parts during this time period.

**POTENTIAL RISK:** Ventilation delivery to patient is interrupted with audio and visual alarms followed by the opening of the Safety Valve. Patient harm may occur if alternative ventilation is not provided by healthcare professional.

### **ACTIONS TO BE TAKEN BY CAREFUSION:**

CareFusion will contact your facility by telephone to coordinate implementation of the corrective action at your site.

### **ACTION TO BE TAKEN BY THE CUSTOMER**

- Please promptly return the enclosed response card to expedite the correction process and acknowledge receipt of this notification.

- CareFusion does not require that you return your devices.
- You will be contacted by a member of the CareFusion Recall Support Center to arrange for onsite remediation of the affected devices, in the interim if any AVEA ventilator unit in your facility exhibits a sustained Extended High Ppeak alarm followed by the opening of the Safety Valve, remove the ventilator from service, provide alternate ventilation and contact CareFusion Technical Support per the contact information listed below to report the issue.
- All ventilator-dependent patients should be constantly monitored by qualified personnel to ensure that if a malfunction were to occur, alternate ventilation can be provided.

The US Food and Drug Administration have been notified of this action. 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:

- Web: MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
- Phone: 1800-FDA-1088
- Fax: 1-800-0178, or by
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787


Please use the chart provided below for questions and support (6:30am -5:00pm PDST).

CareFusion Contact	Contact Information	Areas of Support
CareFusion Recall Support Center	<b>888.562.6018</b> <b>858.617.5300</b> <b><a href="mailto:SupportCenter@carefusion.com">SupportCenter@carefusion.com</a></b>	Recall Related Questions
CareFusion Technical Support/Customer Advocacy	<b>800.231.2466</b> <b>714.283.2228</b> <b><a href="mailto:support.vent.us@carefusion.com">support.vent.us@carefusion.com</a></b>	Product Technical Support Adverse Event Reporting

Please promptly return the enclosed response card to expedite the correction process and acknowledge receipt of this notification.

We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

Sincerely,

  
 Charles Nehring  
 Vice President, Quality and Regulatory Affairs  
 CareFusion – Respiratory Systems

Enclosed: List of affected units, customer response card