



URGENT PRODUCT RECALL

Date: September, 2011

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

Dear Business Partner:

We have identified a potential risk associated with certain AVEA® ventilators and affected replacement parts manufactured between March 1, 2009 and June 30, 2011. We are implementing a voluntary Field Safety Corrective Action.

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.

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.

AFFECTED UNITS: Please see enclosed.

ACTIONS TO BE TAKEN BY BUSINESS PARTNERS:

- CareFusion does not require that you or your customers return your devices to CareFusion.
- Return response cards immediately to CareFusion at address provided.
- Forward enclosed customer letter and response cards to your affected customers.

Customers should be notified that if an AVEA ventilator unit exhibits a sustained Extended High Ppeak alarm followed by the opening of the Safety Valve, remove the ventilator from service and provide alternate ventilation. 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.

ACTIONS TO BE TAKEN BY CAREFUSION

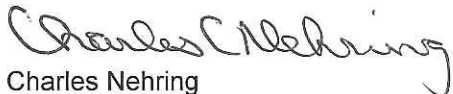
At receipt of your response cards, the CareFusion Recall Support Center will contact you by telephone to coordinate implementation of the corrective action.

You will be provided a list of FAQ's to assist with customer inquiries. For additional assistance please contact Technical Support at the below details.

CareFusion Contact	Contact Information	Areas of Support
CareFusion Recall Support Center	888.562.6018 <u>SupportCenter@carefusion.com</u>	Recall Related Questions
CareFusion Technical Support/Customer Advocacy	800.231.2466 <u>support.vent.us@carefusion.com</u>	Product Technical Support Adverse Event Reporting

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

Sincerely,



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

Enclosed: List of affected units, customer response card, and customer letter