URGENT FIELD SAFETY NOTICE

Date: September 12, 2011

Legal Manufacturer:
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 minimize the risk.

Product Reference: Model numbers 17310, 17311, 17312, 17610, 17611, and 17612

Serial Number: Please see enclosed

FSCA Identifier: RES2011-AVEA-01

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.

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 Technical Support Department 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 and provide alternate ventilation.
    - Remove the ventilator from service and contact CareFusion Technical Support or local Business partner 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.

ACTIONS TO BE TAKEN BY CAREFUSION OR REPRESENTATIVE
At receipt of your response card, CareFusion or its local business partner will contact your facility by telephone to coordinate implementation of the corrective action at your site.

CareFusion Technical Support	+49 931 4972 393 Support.CC.EU@carefusion.com	Recall Related Questions
Name of CareFusion Business Partner	*Contact Information of Business Partner*	Recall Related Questions

Should you have any questions, please contact CareFusion's Technical Support Department or your CareFusion Business Partner.

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

Sincerely,

[redacted]
Vice President, QRA Respiratory & Gort Operations
CareFusion International

Enclosed: Serial number list of affected units, customer response card

Appendix 1

FIELD SAFETY NOTICE
AVEA® Ventilators

Acknowledgment and Verification Form

Product Name: AVEA ventilators

Product Reference: 17310, 17311, 17312, 17610, 17611 and 17612

FSCA Identifier: RES2011-AVEA-01

Name of Hospital / Facility	
Hospital / Facility Address	
Name	
Telephone number	
Email address	
Signature	
Date	

☐ I have read and understand the contents of this Field Safety Notice and confirm that our medical equipment inventory has been checked, and we no longer have in service the list of effected ventilators.

☐ I have read and understood the contents of this Field Safety Notice and confirm that our inventory has been checked and we have the following equipment :

Model Number	Serial Number

Note: If more space is needed for the above table please attach a separate document.

The following person has to be contacted to coordinate the action (please complete if different than above)

Name	
Telephone Number	
Email	

Please return this form to:
(Return of your product is not necessary)
Address: