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## URGENT FIELD SAFETY NOTICE

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April 21, 2015

FSCA-RES2015-AVEA-01

Dear Valued Customer:

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

CareFusion has identified a potential risk associated with AVEA® Ventilator caused by a malfunction of a pressure transducer. The malfunctioning pressure transducer is detected and by design ceases ventilation and opens the safety valve to atmosphere allowing spontaneous breathing of patients capable of doing so.

Serial Number(s): Reference enclosed

### **Problem and Affected Devices**

#### **ISSUE:**

When the AVEA® Ventilator develops a malfunction of the pressure transducer in the ventilator that measures the inspiratory or expiratory pressure of the circuit, a false alarm is initiated indicating an Ext High Ppeak or Circuit Occlusion depending on the specific failure mode within the pressure transducer.

CareFusion is voluntarily performing a Field Safety Corrective Action to correct affected devices subject to this potential risk.

#### **POTENTIAL RISK:**

Most reports of Ext High Ppeak or Circuit Occlusion alarms have been detected prior to use of the ventilator on a patient. If a malfunction occurs, a delay of initiation of ventilation may result. Under these circumstances, the ventilator by design will alarm and cease ventilation. The safety valve will open allowing patients that can spontaneously breathe to do so.

The reported rate of occurrence is very low with zero (0) reports of patient injury received to-date.

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

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

**ACTION TO BE TAKEN BY THE CUSTOMER**

- CareFusion does not require that you return your devices.
- Please promptly return the enclosed response card to expedite the correction process and acknowledge receipt of this notification.
- You will be contacted by your CareFusion distributor to arrange for onsite remediation of the affected devices, in the interim if any AVEA ventilator unit in your facility exhibits a sustained Ext High Ppeak or Circuit Occlusion alarm followed by the opening of the Safety Valve, that cannot be cleared by powering the ventilator off and back on again, immediately remove the ventilator from service, provide alternate ventilation and contact your distributor or CareFusion Technical Support per the contact information listed below to report the issue.

Please use the chart provided below for questions and support

CareFusion Contact	Contact Information	Areas of Support
CareFusion Technical Support	+49 931 4972 393 <a href="mailto:Support.CC.EU@carefusion.com">Support.CC.EU@carefusion.com</a>	FSCA Related Questions
<i>Name of CareFusion Business Partner</i>	<b>Contact information of Business Partner</b>	Product Technical Support Adverse Event Reporting

Please promptly return the enclosed Response Card to your distributor 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



Detlef Grotheer  
Director Quality Assurance, RDx  
Respiratory Solutions

Enclosed: List of affected units, customer response card