

## El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Ventilador Pulmonar
<b>NO. IDENTIFICACIÓN RISARH</b>	I1502-94
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	CareFusion 3100A y 3100B
<b>REGISTRO SANITARIO</b>	2008EBC-0001778
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Proporcionan ventilación asistida en el tratamiento de pacientes infantiles, pediátricos, adultos en cuidado intensivo con insuficiencia respiratoria
<b>NOMBRE DEL FABRICANTE</b>	Carefusion/ Cardinal Health/ Viasys Respiratory Care/ Viasys Health Care
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante afirma que el nuevo diafragma/CAP desarrollado para los equipos referenciados ha eliminado las fugas accidentales, lo que se puede traducir en un aumento de la presión media de la vía aérea (mPaw) durante la calibración, el intervalo máximo aceptable será de 10 cmH <sub>2</sub> O para lo cual se debe ajustar los reguladores de presión para compensar, de lo contrario se puede conllevar a un retraso en la aplicación del tratamiento clínico o que se presenten potencialmente eventos adversos sobre el paciente.
<b>FUENTE</b>	ANEXO 1
<b>FECHA DE NOTIFICACION</b>	27 de Febrero de 2015

### RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico [tecnovigilancia@invima.gov.co](mailto:tecnovigilancia@invima.gov.co)

## ANEXO 1

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### [High Priority] - A23898 : CareFusion—3100A and 3100B High Frequency Oscillatory Ventilators: Higher mPaw or Amplitude/Delta P Measurements May Occur During Calibration Medical Device Ongoing Action

**UMDNS Terms:**

- Ventilators, Intensive Care, Neonatal/Pediatric, High-Frequency [18793]

**Product Identifier:** High Frequency Oscillatory Ventilators (HFOVs): (1) 3100A, (2) 3100B [*Capital Equipment*]

**Geographic Regions:** Worldwide

**Manufacturer(s):** CareFusion Corp 3750 Torrey View Ct, San Diego, CA 92130, United States

**Suggested Distribution:** Clinical/Biomedical Engineering, Pulmonology/Respiratory Therapy, NICU

**Problem:** In a February 18, 2015, letter submitted by an ECRI Institute member hospital, CareFusion states that the new cap/diaphragm for the above systems has eliminated unintentional leaks, which may result in higher mPaw or Amplitude/Delta P measurements during calibration. This problem may result in higher pressures on the pre-use checks than the acceptable range. CareFusion states that these higher pressures do not mean the ventilator is malfunctioning. This problem may be the result of the circuit integrity becoming very efficient because of the reduction of leaks in the improved cap/diaphragm design. CareFusion states that the acceptable range for the mean and the Amplitude/Delta P will be 10 cmH<sub>2</sub>O higher than the ranges stated on the label.

**Action Needed:**

Identify any affected product in your inventory. If you have affected product, verify that you have received the February 18, 2015, letter from CareFusion. CareFusion states that it will be releasing new Ventilator Performance Check labels. If the ventilator fails any of the pre-use performance checks, CareFusion recommends normal troubleshooting. CareFusion states that some biomedics may have adjusted internal pressure regulators to compensate for older cap/diaphragms, which may need to be readjusted as a result of the new cap/diaphragms.

**For Further Information:**

CareFusion technical support department

Website: [Click here](#)

**Comments:**

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our [HDA Format Guide](#).

**Source(s):**

- 2015 Feb 19. Member Hospital. CareFusion letter submitted by an ECRI Institute member hospital. [Download](#)
- 2015 Feb 20. Manufacturer. The manufacturer confirmed the information in the source material

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