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:

NOMBRE DEL DISPOSITIVO MÉDICO	Ventilador Pulmonar
NO. IDENTIFICACIÓN RISARH	I1405-226
REFERENCIAS DEL DISPOSITIVO MEDICO	CareFusion 3100A y 3100B
REGISTRO SANITARIO	2008EBC-0001778
INDICACIONES Y USO ESTABLECIDOS	Proporcionan ventilación asistida en el tratamiento de pacientes infantiles, pediátricos, adultos en cuidado intensivo con insuficiencia respiratoria.
NOMBRE DEL FABRICANTE	CareFusion / Cardinal Health / Viasys Respiratory Care / Viasys Health Care .
DESCRIPCION DEL PROBLEMA	El fabricante afirma que ha detectado dificultades para llevar a cabo la calibración y presurización del circuito paciente por parte de los usuarios, lo que puede conllevar a un retraso en la aplicación del tratamiento clínico o que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	30 de Mayo de 2014

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

A22390 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: May 29, 2014
UMDNS Terms:
- Ventilators, Intensive Care, Neonatal/Pediatric, High-Frequency [18793]

Suggested Distribution:
- Clinical/Biomedical Engineering
- NICU
- Pulmonology/Respiratory Therapy

Geographic Regions:
- Worldwide

CareFusion—3100A and 3100B High Frequency Oscillatory Ventilators: Manufacturer Issues Information Regarding Air Leak Patient Circuit Calibration and Performance Check

Product Identifier:
High Frequency Oscillatory Ventilators (HFOV): (1) 3100A, (2) 3100B *[Capital Equipment]*
Manufacturer:
- CareFusion Corp3750 Torrey View Ct, San Diego, CA 92130, United States

Summary: On May 29, 2014, the manufacturer confirmed the information provided in the source material.
Problem: In an April 24, 2014, letter submitted by an ECRI Institute member hospital, CareFusion states that it has received reports of difficulty pressurizing patient circuits for the above ventilators during pre-use Patient Circuit Calibration. CareFusion also states that Patient Circuit Calibration and Performance Check are important to ensure the ventilator is ready for clinical use, and failure during these procedures may lead to delay in implementation of clinical treatment. Failure to preform pre-use checks as defined in the Operator's Manual may also cause the ventilator to pressurize incorrectly, potentially leading to damage to the ventilator and delay in treatment. For more information regarding troubleshooting Patient Circuit Calibration failures and common sources of circuit leaks, refer to the letter or the Operator's Manual (available here). CareFusion also states that contributing factors associated with a failure to pressurize, including the common sources of circuit leaks listed in the letter, may be misdiagnosed as the Cap Diaphragm leaking.
Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the April 24, 2014, letter from CareFusion. CareFusion states that it is important that users refer to the Operator's Manual as needed before set-up and/or use of the above ventilators and that it is the user's responsibility to identify and eliminate all possible contributing factors associated with a failure to pressurize.
For Further Information:
CareFusion
Website: Click here

Comment:
- 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):
- 2014 May 28. Member Hospital. CareFusion letter submitted by an ECRI Institute member hospital.
- 2014 May 29. Manufacturer. The manufacturer confirmed the information.