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	Bomba de infusion ALARIS MEDICAL SYSTEM CARDINAL HEALTH
NO. IDENTIFICACIÓN RISARH	I1401-25
REFERENCIAS DEL DISPOSITIVO MEDICO	8100 LVP
REGISTRO SANITARIO	2010EBC-0005493
INDICACIONES Y USO ESTABLECIDOS	Este equipo es usado para facilitar la administración parenteral (intravenosa, subcutánea, intraperitoneal, intrarraquídea) de drogas y soluciones. Es usado donde es esencial la precisión y un aporte constante.
NOMBRE DEL FABRICANTE	Carefusion UK232
DESCRIPCION DEL PROBLEMA	Se manifestó por parte del fabricante que se pueden presentar rupturas por encima de la bisagra inferior de la puerta del equipo biomédico antes mencionado, generando que la placa interior no sea segura y la precisión del flujo se vea comprometida, lo que puede conllevar a posibles eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	22 de Enero 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

S0251 - Normal Priority Medical Device Alert

Medical Device Special Report
Updated: January 9, 2014
UMDNS Terms:
- Infusion Pumps, Multitherapy, Large Volume, Multichannel [17634]

Suggested Distribution:
- Clinical/Biomedical Engineering
- IV Therapy
- Nursing

Geographic Regions:
- Worldwide

ECRI Institute User Experience Network—Lower Door Hinge May Crack on Carefusion Alaris 8100 Pump Modules

Product Identifier:
Model 8100 Alaris LVP Infusion Pump Modules *[Capital Equipment]*
Manufacturer:
- CareFusion Alaris3750 Torrey View Ct, San Diego, CA 92130-2622,

Problem:
A member facility reports finding multiple CareFusion Alaris large-volume pump (LVP) modules with the lower left portion of the door cracked and chipped (see Figure 1). There are no reported injuries resulting from this problem.

Figure 1. Alaris Pump Module Door Hinge Chip

Discussion

CareFusion is currently investigating this problem. The damage occurs above the door's lower hinge. In most cases, the damage does not prevent the door from closing or latching. However, CareFusion has received a limited number of reports of the hinge breaking off when impacted. If the hinge breaks off, CareFusion recommends removing the module from service. In this scenario, a clinician may try to position the door so that it will latch; however, the lower portion of the door's inner platen may not be secure and flow accuracy may be compromised.

The member reports that 40% of their modules are affected but that no hinges have broken off. CareFusion provides replacement doors free of charge; the doors can be installed by clinical engineering. CareFusion indicates that this problem has been corrected in newly manufactured modules.

ECRI Institute Recommendations:
ECRI Institute recommends the following for users of the CareFusion Alaris System LVP:
- Do not use a LVP module in which the hinge has broken off. Remove the module from service until the door is replaced.
- Schedule repair for modules with cracked or chipped doors.

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 Jan 9. ECRI Institute researched member report.