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 Infusión CAESAREA
NO. IDENTIFICACIÓN RISARH	I1402-68
REFERENCIAS DEL DISPOSITIVO MEDICO	BODYGUARD 575
REGISTRO SANITARIO	INVIMA 2009EBC-0005004
INDICACIONES Y USO ESTABLECIDOS	Este equipo está diseñado para la infusión de medicamentos o fluidos que requieren ser suministrados de forma continua o intermitente con tasas de infusión precisas y controladas a través de rutas clínicamente aceptables, incluyendo vías intravenosas, subcutáneas, percutáneas, intrarterial, epidural, enteral, en proximidad a los nervios y dentro de un sitio intraoperatorio
NOMBRE DEL FABRICANTE	Caesarea Medical Electronics Ltd.
DESCRIPCION DEL PROBLEMA	Menciona que las baterías de Litio presentan deformación al aumentar sus dimensiones por reacciones químicas al interior de la misma, lo que puede separar la carcaza de la bomba o provocar el mal funcionamiento del equipo biomédico, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	Anexo
FECHA DE NOTIFICACION	14 de Febrero 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

S0252 - Normal Priority Medical Device Alert

Medical Device Special Report

Updated: February 13, 2014

UMDNS Terms:
- Batteries [16640]
- Infusion Pumps, Analgesic, Patient-Controlled [16924]
- Infusion Pumps, Analgesic, Patient-Controlled, Ambulatory [28080]

Suggested Distribution:
- Anesthesia
- Clinical/Biomedical Engineering
- Critical Care
- Emergency/Outpatient Services
- Home Care
- Internal Medicine
- IV Therapy
- Materials Management
- Nursing
- Obstetrics/Gynecology /Labor and Delivery
- OR/Surgery
- Pain Clinic

Geographic Regions:
- Worldwide

ECRI Institute User Experience Network—Swollen Li-Polymer Batteries in CME BodyGuard 575 Infusion Pumps May Affect Performance

Product Identifier:

Model 130-050XA Li-Polymer 1800 mA Batteries used with BodyGuard 575 Infusion Pumps *[Consumable, Capital Equipment]*

Manufacturer:
- Caesarea Medical Electronics Ltd16 Shacham Street, IL-38900 Caesarea, Israel

Problem:

The lithium polymer batteries in the above infusion pumps may be difficult to remove as a result of swelling. The pump may not power on because of the swollen battery.

Discussion

An ECRI Institute member hospital reported that when replacing the Li-Polymer batteries of five BodyGuard 575 infusion pumps as part of scheduled preventive maintenance, the batteries were difficult to remove as a result of swelling. Upon removal, the batteries continued to swell until the plastic casing separated (see Figure 1).

Figure 1. Separated casing as a result of Li-Polymer battery swelling.

Lithium battery swelling is indicative of internal damage as a result of chemical reaction. The problem reporter claims that this battery swelling caused one pump to not turn on and forced visible expansion of the battery compartment. Pump performance was not adversely affected in the other four inspected pumps. All pumps were undamaged and continued to function normally after replacement batteries were installed. CME recommends battery replacement every 2 years; however, this swelling occurred after approximately 21 months of use.

Supplier Response/Perspective

CME states that lithium polymer batteries swell upon failure, although this should occur only at a low percentage. The batteries should last more than 24 months, but this is contingent on the conditions under which the batteries are stored and charged, conditions that may also affect overall performance. The manufacturer claims to have installed all possible protective overcharging measures in both the battery and the pump and is unaware of any additional means of preventing the battery from swelling.
CME states that it is unaware of any risk of patient injury or pump damage associated with this issue and that the problem should not interfere with pump operation.
The manufacturer states that it is aware of 2 reports of battery failure leading to fire within the last 10 years, but an investigation determined that the batteries had been used under abnormal conditions or the user had made unauthorized changes.
CME states that the warranty period for the batteries is 12 months and that swollen batteries should be replaced and returned to CME or its distributors.

ECRI Institute Recommendations:

ECRI Institute recommends the following:
- Instruct clinical engineering staff to inspect BodyGuard 575 infusion pumps for battery swelling during pump maintenance. Replace affected batteries using appropriate personal protective equipment in the case of any leaking chemicals (per MSDS). These chemicals may be hazardous and should not be touched. The battery's material safety sheet (MSDS) will identify the specific hazards and precautions.
- Contact CME for replacement and return of swollen batteries.

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 Feb 13. ECRI Institute researched member report.
- 2014 Feb 13. Figure 1.