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	Camas Hospitalarias
NO. IDENTIFICACIÓN RISARH	I1407-299
REFERENCIAS DEL DISPOSITIVO MEDICO	2130, 2131, 2140, 2141, 2151, 2152, 2155 y 2156.
REGISTRO SANITARIO	2013DM-0009676
INDICACIONES Y USO ESTABLECIDOS	Camas y camillas para uso hospitalario.
NOMBRE DEL FABRICANTE	Stryker Medical Muka Metal Ticaret Ve Sanayi A.S.
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha detectado problemas mecánicos en los sistemas de freno causando una reducción considerable de su funcionamiento, atribuible a un error de uso cuando los frenos eléctricos son activados durante el movimiento de la cama, lo que puede conllevar a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	18 de Julio 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

ANEXO 1

A22655 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: July 8, 2014
UMDNS Terms:
- Beds, Electric [10347]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Critical Care
- Facilities/Building Management
- Home Care
- OR/Surgery

Geographic Regions:
- Africa
- Argentina
- Australia
- Brazil
- Canada
- Chile
- China
- Europe
- Japan
- Korea
- Latin America
- Mexico
- Middle East
- Singapore
- South Africa
- Taiwan
- U.K.
- U.S.

Stryker—InTouch Critical Care Beds: Casters May Break if Brake System Is Activated While Bed Is in Motion

Product Identifier:
InTouch Critical Care Beds *[Capital Equipment]*
Model Nos.: 2130, 2131, 2140, 2141, 2151, 2152, 2155, 2156
For affected serial numbers, see the Serial Number Listing sent to your facility.

Manufacturer:
- Stryker Medical3800 E Centre Ave, Portage, MI 49002, United States

Problem:
In a June 30, 2014, Urgent Medical Device Notification letter submitted by ECRI Institute member hospitals, Stryker states that it has received reports of incidents in which a caster on the above beds has broken on top of the caster stem where the brake rod inserts into the caster. Strykers states that these broken casters are identified when the beds are hoisted or lifted from the floor during regular maintenance. If more than one caster on a unit is damaged, brake functions may be affected and result in reduced brake holding force. Stryker also states that if only one caster on the bed is damaged, brake functionality continues to meet specifications. Stryker further states that the root cause of this problem is attributable to a potential use error in which the bed's electric brakes are activated while the bed is in motion.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the June 30, 2014, Urgent Medical Device Notification letter, operation instructions, brake labels and application instructions, and business reply form from Stryker. Stryker states that the caster braking system on the above beds is designed to be activated when the bed is in a stationary position, as stated in the operations manual. When transporting the bed, the bed should be brought to a complete stop before applying the bed's caster brake system. The caster brake system is intended to keep the bed from moving while in a stationary position. Complete the business reply form, and return it to Stryker using the instructions on the form. Affix the brake labels to the bed control panel using the instructions provided with the labels.

For Further Information:
Stryker customer service department
Tel.: (800) 327-0770, 8 am. to 6 p.m. Eastern time, Monday through Friday
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 Jul 7. Member Hospital. Stryker letter submitted by ECRI Institute member hospitals (includes reply form)
- 2014 Jul 8. Manufacturer. Manufacturer confirmed information