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 STRYKER
NO. IDENTIFICACIÓN RISARH	I1505-212
REFERENCIAS DEL DISPOSITIVO MEDICO	InTouch
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 establece que el cable que conecta el control de mano con la cama, puede ingresar en el carril lateral de desplazamiento y ser aprisionado durante los movimientos de elevación y descenso de la cama, ocasionando la exposición de los filamentos conductores del mismo, conllevando a que se presenten potencialmente eventos adversos sobre los pacientes o usuarios.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	20 de Mayo 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

ANEXO 1

[Normal Priority] - S0274 : Stryker—InTouch Beds: Pendant Cord May Be Damaged if Routed Between Side Rail and Bed Frame [ECRI Institute User Experience Network]

Medical Device Special Report

Published: Thursday, May 14, 2015

UMDNS Terms:

- Beds, Electric [10347]

Product Identifier:
InTouch Critical Care Beds *[Capital Equipment]*

Geographic Regions: Worldwide

Manufacturer(s): Stryker Corp2825 Airview Blvd, Kalamazoo, MI 49002, United States

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Nursing

Problem:

- If the pendant cord (which connects the hand pendant control to the bed frame) is routed between the side rail and the frame of the above beds, the cord insulation may fray due to the side rail rubbing against the cord during repeated raising and lowering of the rails.
- The cord may become damaged to the point where wires will be exposed.

Manufacturer's Corrective Action/Recommendations:

- Stryker states that the solution to this problem is typically to route the cord differently. Stryker does not install the pendant/cord, but can assist by sending a service technician to the hospital to help find better cord routes.
- The pendant is a low voltage pendant so there is no danger to touching exposed wires on the pendant cord. Stryker has also stated that the pendant ceasing to function properly will not affect other bed functions.

ECRI Institute Recommendations:

1. Do not route the pendant cord between the bed side rails and frame, and alert all users of the Stryker InTouch Critical Care Bed that the pendant cord insulation may fray and expose the cord wires if it is routed between the bed side rails and frame.
2. If you are having issues finding a proper route for the pendant cord, contact Stryker Medical Technical Support by telephone at (800) 327-0770.

Background:

- ECRI Institute received multiple reports of Stryker InTouch Critical Care Bed pendants being damaged by being caught in between the side rail and frame.
- One of the reporting hospitals now routes the cord under and through a gap in the side rail (Figure 1), which has alleviated the problem. However, with this new route, the cord occasionally snags door handles or other objects when transporting the bed.

Figure 1. Updated cord routing strategy used by reporting hospital.

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 May 14. ECRI Institute researched member report.
- 2015 May 14. Figure 1. Download