# 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** | I1409-367 |
| **REFERENCIAS DEL DISPOSITIVO MEDICO** | AFFINITY modelos P3700B, P3700C, P3700D y P3700E, fabricadas entre octubre de 2006 y junio de 2014. |
| **REGISTRO SANITARIO** | 2013DM-0010757 |
| **INDICACIONES Y USO ESTABLECIDOS** | Las camas obstétricas AFFINITY™ FOUR están destinadas a utilizarse como camas de partos para mujeres embarazadas con un cuadro LDR (dilatación, parto y recuperación) o LDRP (dilatación, parto, recuperación y posparto). Los sistemas de cama hospitalaria VERSACARE™ Y TOTALCARE™ son sistemas que ofrecen soporte para pacientes perfectamente adaptado a los entornos hospitalarios. Pueden utilizarse en unidades de cuidados y vigilancia intensiva, atención medico quirúrgica, unidad de cuidados pos anestesia y salas de urgencias, entre otros. La cama PROGRESSA™ está diseñada para la prevención o el tratamiento de complicaciones pulmonares u otras complicaciones asociadas con la inmovilidad; para el tratamiento o la prevención de úlceras por presión; o para cualquier otro uso donde pueden obtenerse beneficios médicos a partir de la terapia de rotación lateral continua o la terapia de rotación/percusión. |
| **NOMBRE DEL FABRICANTE** | Hill Rom Inc |
| **DESCRIPCION DEL PROBLEMA** | El fabricante emite ciertas recomendaciones para evitar el deterioro de los sistemas de enganche de la sección de pies del dispositivo producido por someterlos a constantes golpes y caídas, conllevando a que se presenten posibles eventos adversos sobre los pacientes o usuarios. |
| **FUENTE** | ANEXO 1 |
| **FECHA DE NOTIFICACION** | 08 de Septiembre 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

**A22618 01 - Normal Priority Medical Device Alert**

**Medical Device Ongoing Action**
**Updated:** September 2, 2014
**UMDNS Terms:**
- Beds, Electric, Birthing [15732]

**Suggested Distribution:**
- Clinical/Biomedical Engineering
- Facilities/Building Management
- Nursing
- Obstetrics/Gynecology /Labor and Delivery

**Geographic Regions:**
- Worldwide

## Hill-Rom—Affinity Four Birthing Beds: Improper Handling of Lift-Off Foot Section May Cause Attachment Latch Mechanism to Bend

**Product Identifier:**
Affinity Four Birthing Beds [Capital Equipment]
Model Nos.: P3700B, P3700C, P3700D, P3700E
Units manufactured between October 2006 and June 2014

**Manufacturer:**
- Hill-Rom Co Inc1069 State Rt 46 E, Batesville, IN 47006-9164, United States

**Summary:**
This Alert provides additional information based on FDA Center for Devices and Radiological Health (CDRH) source material regarding Alert Accession No. A22618. FDA's CDRH also states that the manufacturer initiated a correction by Urgent Field Safety Notice letter dated June 26, 2014. Additional information is provided in the Geographic Regions field (see bolded region).

**Problem:**
[July 2, 2014]
In a June 25, 2014, Urgent Field Safety Notice letter submitted by ECRI Institute member hospitals, Hill-Rom reminds users of proper handling instructions (located in the user manual) of the lift-off foot section of the above beds. Specifically, Hill-Rom states that improper handling, such as allowing the foot section to be dropped repeatedly, may cause the attachment latch mechanism to become bent. Hill-Rom also states that if the latch mechanism is bent too much, it could potentially cause the installed foot section to be improperly engaged to the bed. If the damaged foot section were to disengage during use, the user may be injured by the foot section falling. Hill-Rom further states that the occurrence of this problem is rare (approximately 2.8 times per million usages, according to the firm's data) and can be avoided by properly handling the foot section and not allowing it to repeatedly drop onto the floor.

**Action Needed:**
The following actions are those listed in Alert Accession No. A22618. Identify any affected product in your inventory. Hill-Rom recommends that you verify that the lift-off foot section on your beds has enough engagement by performing the following steps (for illustrations, see the images in the Urgent Field Safety Notice letter); however, before performing these steps, be aware that the foot section has the potential to fall if the brackets are bent:
(1) Following the procedures in the user manual, remove the lift-off foot section and place it on the perineal stand.
(2) Unsnap and remove the top cushion from the lift-off foot section.
(3) Remove the placenta basin.
(4) Install the lift-off foot section without the cushion back onto the bed frame. Ensure that the latches engage before applying weight or moving around the section.
(5) Push the lift-off foot section all the way to either the left or the right.
(6) If the foot section remains engaged, move on to step 7; if not, contact the Hill-Rom technical support department using the information below.
(7) Verify that the foot support brackets are still solidly engaged in the receivers. Take steps to avoid injury to your lower extremities in case the foot section should fall.
(8) Use 2 hands and press down firmly on the foot section where indicated by "PRESS HERE TO TEST" in the image in the Urgent Field Safety Notice letter; it should not slip or fall.
If the lift-off foot section fails to meet the inspection criteria, take the lift-off foot section and/or bed out of service until a qualified Hill-Rom technician can make the necessary correction. Hill-Rom states that it is working on a way to mitigate this risk through a change to the lift-off foot section. In the meantime, users of affected product (e.g., caregivers, housekeepers) should continue to follow the instructions in the user manual (USR025), specifically the following:
(1) Grasp both handles, and hold the foot section as close to the body as possible.

(2) Lift and slide the foot section toward you (bending your knees) while taking a step backward.
(3) With the knees bent, place the foot section on the floor with the perineal stand down to hold it upright (for illustrations of the these steps, see the images in the Urgent Field Safety Notice letter).
Notify all relevant personnel at your facility of the information in the Urgent Field Safety Notice letter. U.S. customers should report adverse reactions or product quality problems relating to the use of affected product to FDA's MedWatch Adverse Event Reporting program by fax at (800) 332-0178; by mail (using postage-paid FDA form 3500, available here) at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website.

**For Further Information:**
Hill-Rom technical support department
Tel.: (800) 445-3720
Website: Click here

**References:**


- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Affinity Four birthing bedf [online]. 2014 Sep 1 [cited 2014 Sep 2]. Available from Internet: Click here.
- Germany. Federal Institute for Drugs and Medical Devices. Urgent safety notice; Corrective action for the Affinity™ Four birthing bed—lift-off foot section, Hill-Rom [online]. 2014 Aug 1 [cited 2014 Aug 13]. Available from Internet: 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 Sep 2. Member Hospital. June 25, 2014, Hill-Rom letter submitted by an ECRI Institute member hospital. Reference No. Mod 1224
- 2014 Sep 2. BfArM (Germany). Reference No. 4474/14
- 2014 Sep 2. BfArM (Germany). Reference No. Mod 1224 (includes reply form)
- 2014 Sep 2. FDA CDRH Database. Class II. Reference No. Z-2562-2014
- 2014 Sep 2. Manufacturer. The manufacturer confirmed the information in the source material.