

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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	Sillas de Ruedas OTTO BOCK
NO. IDENTIFICACIÓN RISARH	I1708-329
REFERENCIAS DEL DISPOSITIVO MEDICO	480A76=00000_K VOYAGER EVO
REGISTRO SANITARIO	2013DM-0010718
INDICACIONES Y USO ESTABLECIDOS	Ayuda técnica para permitir el desplazamiento de personas con problemas de locomoción o movilidad reducida debido a una lesión.
NOMBRE DEL FABRICANTE	Otto Bock Mobility Solutions Gmbh
DESCRIPCION DEL PROBLEMA	El fabricante informa que los tenedores de las ruedas pueden quedar fuera de posición en los dispositivos referenciados, la horquilla de la rueda se desajusta influyendo negativamente en las características de conducción, ocasionando que la parte delantera de la silla descienda y caiga hacia delante, conllevando a que se presenten potenciales eventos adversos sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	01 de Agosto de 2017

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

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ANEXO

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[High Priority] - A28950 : Otto Bock—Voyager Evo Wheelchairs: Caster Fork May Turn Out of Position

Medical Device Ongoing Action

Published: Monday, July 24, 2017

Last Updated: Thursday, July 27, 2017

UMDNS Terms:

- Wheelchairs, Mechanical [16949]

Product Identifier:

Voyager Evo Wheelchairs [Capital Equipment]

Product No. 480A76=00000_K

Geographic Regions: Argentina, Australia, Austria, Belgium, Canada, China, Colombia, Czech Republic, Finland, France, Germany, Hong Kong, Hungary, Ireland, Italy, Korea, Luxembourg, Mexico, The Netherlands, Poland, Romania, Russia, Singapore, Slovakia, South Africa, Switzerland, Thailand, U.K.

Manufacturer(s): Otto Bock HealthCare GmbH Max-Naeder-Strasse 15, Duderstadt, D-37115, Germany

Suggested Distribution: Clinical/Biomedical Engineering, Facilities/Building Management, Home Care, Physical Therapy/Rehabilitation

Problem:

In a July 7, 2017, Urgent Safety Information letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Otto Bock states that the caster forks may turn out of position on the above wheelchairs, potentially causing connections to become loose and the castor fork to go out of adjustment. This may negatively influence driving characteristics and potentially lead to the front of the wheelchair dropping down and falling forward. Otto Bock also states that this problem may be caused by adjusting the caster journal angle after optimizing the user's sitting position.

Action Needed: Identify any affected wheelchairs in your inventory and identify any patients using affected wheelchairs. If you have affected wheelchairs and/or affected patients, verify that you have received the July 7, 2017, Urgent Safety Information letter from Otto Bock. Regularly check the alignment of the caster fork axis and watch for changed driving characteristics and/or play between the components during use. If you identify this failure mode on a wheelchair, contact your Otto Bock local distributor. Inform all users of the information in the letter.

For Further Information:

Otto Bock customer care center

Tel.: 49 (69) 9999394

E-mail: ccc@ottobock.de

Website: [Click here](#)

References:

- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for Voyager Evo Starrrahmenrollstuhl by Otto Bock Mobility Solutions [online]. 2017 Jul 14 [cited 2017 Jul 19]. Available from Internet: [Click here](#).

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):

- 2017 Jul 19. BfArM (Germany). 06599/17 [Download](#)
- 2017 Jul 19. BfArM (Germany). [Download](#)
- 2017 Jul 24. Manufacturer. Manufacturer confirmed information