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	Sistemas de Compresión Neumática Intermitente FLOWTRON ARJOHUNTLEIGH
NO. IDENTIFICACIÓN RISARH	I1706-248
REFERENCIAS DEL DISPOSITIVO MEDICO	ACS900 Flowtron, seriales 1400028031 hasta 1600048470, versiones de software V1.099
REGISTRO SANITARIO	2014DM-0011065
INDICACIONES Y USO ESTABLECIDOS	Los sistemas FLOWTRON son sistemas profilácticos y terapéuticos no invasivos para reducir la incidencia de anomalías o deficiencias vasculares y venosas en las extremidades superiores e inferiores, a través de la técnica de compresión neumática intermitente (CNI). La aplicación de compresión neumática externa genera un efecto que simula y/o complementa el sistema natural de retorno venoso que ofrecen los músculos de las extremidades. El sistema cosiste de una bomba y un grupo de vestimentas que pueden ser de pantorrilla, muslo, pie, pierna y brazo.
NOMBRE DEL FABRICANTE	Arjohuntleigh Ab Arjohuntleigh Magog Inc Arjo Hospital Equipment Ab Getinge (Suzhou) Co. Ltd. Arjohungleich Polska Sp. Z.O.O
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos pueden suministrar una presión constante sin que se dispare la alarma, además de que se observa la pantalla LCD en blanco, conllevando a que se presenten posibles eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	23 de Junio de 2017

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO 1

[High Priority] - A28765 : ArjoHuntleigh—Model ACS900 Flowtron Pumps: May Deliver Constant Pressure to Calf Garment without Triggering Alarm

Medical Device Ongoing Action

Published: Thursday, June 22, 2017

UMDNS Terms:

- Circulatory Assist Units, Peripheral Compression, Intermittent [10969]

Product Identifier: Model ACS900 Flowtron Pumps *[Capital Equipment]*
Software Version V1.099; Serial Nos.: 1400028031 through 1600048470 Units manufactured between September 26, 2014, and December 20, 2016

Geographic Regions: Australia, Austria, Bahrain, Brazil, Canada, Chile, Colombia, Cyprus, Czech Republic, Denmark, Ecuador, France, Germany, Greece, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Jordan, Kuwait, Lebanon, Malaysia, Mauritius, Mexico, The Netherlands, New Zealand, Norway, Oman, Pakistan, Paraguay, Poland, Qatar, Saudi Arabia, Singapore, South Africa, Spain, Sweden, Switzerland, Tanzania, United Arab Emirates, U.K., U.S.

Manufacturer(s): ArjoHuntleigh Polska Sp z o o ulica Ks Wawrzyniaka 2, PL-62-052 Komorniki, Poland

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, OR/Surgery, Information Technology, Home Care

Problem:
In an Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), ArjoHuntleigh states that the above pumps may deliver constant pressure to the garment without triggering the alarm, potentially resulting in patient injury. ArjoHuntleigh also states that it has received reports of this problem occurring in conjunction with a blank LCD display.

Action Needed:
Identify any affected pumps in your inventory. If you have affected pumps, verify that you have received the Urgent Field Safety Notice letter and Customer Response Form from ArjoHuntleigh. Upgrading affected pumps to software revision V2.000 will ensure more resilient systems. The firm states that you may continue to use affected pumps until an upgrade can be performed, on the condition that the patient's limbs are monitored frequently and the garments are checked to ensure that they are correctly fitted to the patient and that they are deflating on a regular bases. ArjoHuntleigh also recommends that you check the pump LCD display regularly to ensure that it indicates that the garments are inflating and deflating correctly. Notify all relevant personnel at your facility of the information in the Urgent Field Safety Notice letter, and forward a copy of the letter to any facility to which you may have further transferred affected product. Complete the Customer Response Form, and return it to ArjoHuntleigh using the information on the form. Upon receipt of the form, an ArjoHuntleigh representative will contact your facility to arrange for service and upgrade at no cost. Retain a copy of the letter with your records.
For Further Information:
ArjoHuntleigh
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. ArjoHuntleigh: Flowtron ACS900 [online]. London: Department of Health; 2017 Jun 12 [cited 2017 Jun 19] (Field safety notice; reference no. 2017/006/006/701/008). 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 Jun 19. MHRA FSN. 2017/006/006/701/008 Download
- 2017 Jun 19. MHRA FSN. ArjoHuntleigh Reference No. FSN/SUZ/001-2017 (includes reply form) Download
- 2017 Jun 21. Manufacturer. The manufacturer confirmed the information in the source material.
- 2017 Jun 22. Health Canada Recall Listings. Type II. RA-63684 Download