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	Ventiladores SPACELABS
NO. IDENTIFICACIÓN RISARH	I1505-182
REFERENCIAS DEL DISPOSITIVO MEDICO	BLEASE 700 y BLEASE 900, referente a los Sensores de Flujo Pediátrico
REGISTRO SANITARIO	2009EBC-0003935
INDICACIONES Y USO ESTABLECIDOS	Este equipo se utiliza para la ventilación de pacientes adultos y pediátricos bajo anestesia general.
NOMBRE DEL FABRICANTE	Spacelabs Healthcare, Ltd.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que dichos sensores pueden presentar lecturas de volumen tidal inspiratorio (VTi) y de Volumen tidal espiratorio (Vte), por debajo del valor real entregado, conllevando a que se presenten potencialmente eventos adversos sobre los pacientes.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	08 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

[High Priority] - A24257 : Spacelabs—Pediatric Flow Sensor Kits Used with Blease 700 and 900 Series Ventilators: Monitored VTi and Vte Measurements May Be Out-of-Specification Low Compared to Actual Delivered Volumes

Medical Device Ongoing Action

Published: Wednesday, April 22, 2015

UMDNS Terms:

- Monitoring Systems, Physiologic [12636]
- Ventilators, Anesthesia [10145]

Product Identifier:
Pediatric Flow Sensor Kits used with the following Blease Ventilators: (1) 700 Series, (2) 900 Series *[Consumable, Capital Equipment]*
Kit Part No. 376-0561-00
1,040 kits distributed (398 in U.S., 642 outside U.S.)

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Argentina, Brazil, China, Colombia, Ecuador, Finland, India, Libya, Mexico, Nicaragua, Oman, Philippines, Saudi Arabia, Slovakia, Sri Lanka, United Arab Emirates, U.K., U.S., Vietnam

Manufacturer(s): Spacelabs Healthcare IncPO Box 7018, 5150 220th Ave SE, Issaquah, WA 98027-7018, United States

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, OR/Surgery, Pediatrics, Pulmonology/Respiratory Therapy, Materials Management

Problem:
FDA's Center for Devices and Radiological Health states that the monitored inspiratory tidal volume (VTi) and expiratory tidal volume (Vte) measurements reported by the above flow sensors may be out-of-specification low compared to the actual delivered volumes being administered to the patient. FDA's CDRH also states that there have been 2 reports of inaccurate low flow readings. FDA's CDRH further states that the manufacturer initiated a correction by Urgent Medical Device Correction letter dated March 17, 2015, to customers in the U.S. and that Spacelabs e-mailed the letter to international subsidiaries and distributors on March 20, 2015. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the Urgent Medical Device Correction letter and Business Reply Form from Spacelabs. Dispose of affected pediatric flow sensors. Complete the Business Reply Form, and return it to the Spacelabs Global Tech Support department by fax at (425) 363-5758 or by e-mail at techsupport@spacelabs.com . Spacelabs will provide your facility with replacement pediatric flow sensors (part number 376-0561-01). The new sensors will be marked with "-01" molded into the body.

For Further Information:
Spacelabs technical support department
Tel.: (800) 522-7025 (select option 2)
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Spacelabs pediatric flow sensor kit [online]. 2015 Apr 20 [cited 2015 Apr 21]. 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):

- 2015 Apr 21. FDA CDRH Database. Class II. Z-1458-2015 Download