

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una alerta asociada a:

| | |
|---|--|
| NOMBRE DEL DISPOSITIVO MÉDICO | Circuito Ventilatorio para Ventilador OXYLOG |
| NO. IDENTIFICACIÓN RISARH | A1406-233 |
| REFERENCIAS DEL DISPOSITIVO MEDICO | 2000 PLUS / numero de parte: 2M86791 y 2M86841, lotes: 330384.001 hasta 331661.002 |
| REGISTRO SANITARIO | 2009EBC-0003111 |
| INDICACIONES Y USO ESTABLECIDOS | Indicado para ventilación de emergencias y transporte ciclado por tiempo, controlado por volumen y presión de soporte para pacientes que necesitan ventilación obligatoria o asistida. |
| NOMBRE DEL FABRICANTE | Dräger Medical GmbH |
| DESCRIPCION DEL PROBLEMA | El fabricante informa que los circuitos ventilatorios usados en los equipos anteriores identificados con numero de parte “2M86791 y 2M86841” lotes “330384.001 hasta 331661.002” pueden presentar residuos de adhesivo el cual al desprenderse puede ingresar a los pulmones, lo que conllevaría a potenciales eventos adversos sobre el paciente. |
| FUENTE | ANEXO 1 |
| FECHA DE NOTIFICACION | 06 de Junio 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

ANEXO 1

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A22395 - High Priority Medical Device Alert

**Medical Device
Ongoing Action**

Updated: June 2, 2014

UMDNS Terms:

- Ventilators, Transport [18098]
- Breathing Circuits, Ventilator [15003]

Suggested Distribution:

- Clinical/Biomedical Engineering
- Critical Care
- Emergency/Outpatient Services
- Materials Management
- Nursing
- Pulmonology/Respiratory Therapy

Geographic Regions:

- Australia
- Austria
- Belgium
- Chile
- Colombia
- Croatia
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Guadeloupe
- India
- Ireland
- Italy
- Japan
- Kazakhstan
- Martinique
- Mexico
- The Netherlands
- New Zealand
- Norway
- Poland
- Portugal
- Romania
- Saudi Arabia
- Singapore
- South Africa
- Spain
- Sweden
- Switzerland
- Turkey
- U.K.
- United Arab Emirates

Draeger—VentStar Disposable Ventilation Hoses Used with Oxylog 2000 Ventilators: Adhesive Residue May Become Loose

Product Identifier:

| VentStar Disposable Ventilation Hoses used with Oxylog 2000 Ventilators: | Part Nos.: | Batch Nos.: |
|--|------------|-------------------------------|
| Hose Packaging | 2M86791 | 330384.001 through 331661.002 |
| Packaging Box Set | 2M86841 | 330384.001 through 331661.002 |

[Consumable, Capital Equipment]

Units manufactured between January 2013 and April 2014

Manufacturer:

- Draeger Medical Deutschland GmbH Moislinger Allee 53-55, Luebeck, D-23558, Germany

Problem: In a May 2014 Important Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Draeger states that adhesive residue in the above hoses may become loose. If the hose is used, the loose residue could potentially enter the patient's lungs. Draeger states that too much adhesive may have been applied to the angled connector and may have been pushed to the outside when components were joined. Once the adhesive hardens, excessive adhesive may detach and move within the packaging.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the May 2014 Important Safety Notice letter from Draeger. Check for the presence of residue before using affected product. Draeger states that because residue can move freely within the hose, residue can be removed by holding the hose vertically, with the opening facing down. Draeger further states that if there is any doubt, do not use the hose system. To arrange for replacement of unopened product at no charge, contact your Draeger representative.

For Further Information:

Draeger
Website: [Click here](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Draeger Medical. Breathing system components, circuit breathing, Oxylog 2000 breathing hose [online]. London: Department of Health; 2014 May 29 [cited 2014 May 30]. (Field safety notice; reference no. 2014/005/021/081/009). 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 May 30. MHRA FSN. 2014/005/021/081/009
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- 2014 May 30. MHRA FSN.
- 2014 Jun 2. Manufacturer. Manufacturer confirmed source documents