

RECALL

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 Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Mascaras Unomedical LM INSTRUMENTS
NO. IDENTIFICACIÓN RISARH	R1705-187
REFERENCIAS DEL DISPOSITIVO MEDICO	104-E, 108-E, 3106-E, 106-E, 3230-E, 3226-E, lotes específicos.
REGISTRO SANITARIO	2008DM-0002051
INDICACIONES Y USO ESTABLECIDOS	La intención de usos de la mascarillas de oxígeno es suministrar oxígeno a concentraciones medianas de 40 a 60% y concentraciones altas de 80% a 90% y algunos casos hasta 100%.
NOMBRE DEL FABRICANTE	VBM Medizintechnik Gmbh
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha detectado que el tubo por encima máscaras puede desconectarse de la fuente de oxígeno causando una interrupción en el suministro, conllevando a que potencialmente se presenten eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	31 de Mayo 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 1

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[High Priority] - A28573 01 : Cardinal Health/ ConvaTec—Unomedical Oxygen Masks: Tubing May Disconnect from the Mask Medical Device Ongoing Action

Published: Thursday, May 18, 2017

UMDNS Terms:

- Masks, Air-Oxygen, Partial Rebreathing [12451]
- Masks, Air-Oxygen, Nonrebreathing [12450]

Product Identifier:

Oxygen Masks:	Cardinal Health Catalog Nos.:	Unomedical/ConvaTec Product Nos.:	Lot Nos.:
Elongated (under chin), Adult Medium Concentration, No Tubing	19306	104-E	102339
Nonrebreather Elongated (under chin), Adult High Concentration with 7 ft O ₂ Tubing, Check Valve, 2-Side Valve	19306-108	108-E	100454, 101121, 101665, 105676, 105676
Nonrebreather, Elongated (under chin) Adult High Concentration with 7 ft O ₂ Tubing, Check Valve, 1-Side Valve with Fits-All Connector	3106	3106-E	100272, 100465, 101132, 101616, 101994, 102398, 102788, 103192, 103908, 104078, 104902, 104947, 105189, 105441, 105935
Nonrebreather, Reservoir Bag, Check valve, 1-side Valve with Tubing	19306-106	106-E	100152, 103159, 103527, 104009, 104321, 104701, 105569, 105656, 105675
Rebreather Elongated (under the chin) Pediatric, High Concentration with 7 ft (2.1 m) O ₂ Tubing with Fits-All O ₂ Connector, Check Valve, 1-Side Valve	MK230	3230-E	102605
Rebreather Elongated (underneath chin), Pediatric, High Concentration with 1 ft (2.1 m) O ₂ Tubing with Fits-All O ₂ Connector	MK3226	3226-E	101140, 102282, 102400, 102858, 103273, 103853, 104081, 104654, 104889, 105065, 105190, 105216

[Consumable]

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Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

Distributor(s): • Cardinal Health 7000 Cardinal Pl, Dublin, OH 43017, United States

Manufacturer(s): Unomedical Inc., a ConvaTec Inc. Company 7900 Triad Center Drive Suite 400, Greensboro, NC 27409, United States

Suggested Distribution: Anesthesia, Critical Care, Emergency/Outpatient Services, Nursing, Obstetrics/Gynecology/Labor and Delivery, OR/Surgery, Pediatrics, Pulmonology/Respiratory Therapy, Home Care, EMS/Transport, Materials Management

Summary:

This Alert provides information on a Cardinal Health subrecall of the above oxygen masks. For information on the action initiated by ConvaTec, see [Alert Accession No. A28573](#).

Problem:

[May 18, 2017]

In a May 12, 2017, Urgent Product Recall letter, Cardinal Health initiated a subrecall of the above oxygen masks, which were recalled by ConvaTec. The distributor has not confirmed the information provided in the source material.

[May 18, 2017]

In a May 10, 2017, Urgent Voluntary Medical Device Recall letter and a May 10, 2017, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), ConvaTec states that the tubing may disconnect from the above oxygen masks, causing a disruption in the supply of oxygen to patient airways. The manufacturer has not confirmed the information provided in the source material.

Action Needed:

Identify, isolate, and discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the May 12, 2017, Urgent Product Recall letter, copy of the May 10, 2017, ConvaTec Urgent Voluntary Medical Device Recall letter, and Recall Acknowledgment Form from Cardinal Health. Regardless of whether you have affected product, complete the Recall Acknowledgment Form and return it to Cardinal Health using the instructions on the form. Forward a copy of the letter to any facility to which you have further distributed affected product. To arrange for product return and to obtain credit, contact the Cardinal Health customer service department by telephone at (800) 964-5227 (U.S. hospital customers), at (800) 444-1166 (U.S. federal government facilities), or at (888) 444-5440 (all other customers).

For Further Information:

Joyce Hill, Cardinal Health product quality specialist

Tel.: (800) 292-9332

Website: [Click here](#)

ConvaTec

Website: [Click here](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. ConvaTec: various oxygen masks [online]. London: Department of Health; 2017 May 15 [cited 2017 Mon 15]. (Field safety notice; reference no. 2017/005/009/701/010). 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 May 16. Distributor. May 10, 2017, ConvaTec letter [Download](#)
- 2017 May 16. Distributor. Cardinal Health Event No. 2017-00725 (includes reply form) [Download](#)