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	Sistema de ventilación mecánico para asistencia en cuidado crítico e intermedio
NO. IDENTIFICACIÓN RISARH	I1401-44
REFERENCIAS DEL DISPOSITIVO MEDICO	760 y 840
REGISTRO SANITARIO	2008EBC-0001832
INDICACIONES Y USO ESTABLECIDOS	Entregar gases a la vía respiratoria para asistir o suplir las necesidades básicas en condiciones fisiológicas y respiratorias requeridas por el paciente.
NOMBRE DEL FABRICANTE	Covidien Newport Medical Instruments, Inc. Mallinckrodt Medical Covidien Llc
DESCRIPCION DEL PROBLEMA	Se manifestó por parte del fabricante que los sensores de Oxigeno tienen una vida útil de un (1) año y no de dos (2) años como se indica en los manuales de operación y servicio, la falla de dichos consumibles puede generar problemas con las alarmas del equipo y lecturas erróneas de las concentraciones de oxigeno suministradas, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	31 de Enero 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

A21753 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: January 30, 2014
UMDNS Terms:
- Ventilators, Intensive Care [17429]
- Ventilators, Intensive Care, Neonatal/Pediatric [14361]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Pulmonology/Respiratory Therapy
- Pediatrics
- Nursing
- NICU
- Critical Care
- Emergency/Outpatient Services
- Materials Management

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- Worldwide

Covidien—Oxygen Sensor Used with Puritan Bennett Ventilators: Manufacturer Updates Labeling to Clarify Operational Life

Product Identifier:
Oxygen Sensor (O_2 sensor) used with Puritan Bennett Ventilators: (1) 740, (2) 760, (3) 840 [Consumable, Capital Equipment]
O_2 Sensor Part Nos.: (1 and 2) P/N G-062010-00, (3) P/N 4-072214-00

Manufacturer:
- Covidien (US)15 Hampshire St, Mansfield, MA 02048, United States

Problem:
In a January 24, 2014, Urgent Medical Device Voluntary Field Correction letter submitted by ECRI Institute member hospitals, and posted by the FDA's Center for Devices and Radiological Health (CDRH), Covidien states that labeling on the above ventilators has been updated to clarify the operational life of the of the O_2 sensor. Covidien states that the sensors have a life of 1 year from the date of manufacture, depending on operating conditions. A labeling addendum and ventilator operator and service manuals incorrectly states that the O2 sensors should be replaced every 2 years. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected equipment in your facility. If you have affected equipment, verify that you have received the January 24, 2014, Urgent Medical Device Voluntary Field Correction letter and attachment from Covidien. Covidien states that oxygen sensor, P/N 10097559 can be used in the above ventilators. Users of the Puritan Bennet 840 ventilator should discard addendum PN 066009A 09/02 and replace it with the new information in Attachment I of the letter. Users of the Puritan Bennet 740 and 760 ventilators should add the new information in Attachment I to their current operator's manual and service manual. Ensure all O_2 sensors in use or inventory conform to the instructions provided in the letter. Covidien also states that if a sensor becomes nonfunctional during use and cannot be recalibrated, an external oxygen monitoring device with oxygen alarm capability may be required to monitor the supplied level of oxygen from the ventilator and to provide appropriate alarms. A nonfunctional O_2 sensor does not affect the concentration of oxygen delivered from the ventilator and does not control the flow of gases. If a sensor becomes nonfunctional and facility protocol requires transfer of a patient to an alternate ventilator, the patient must be clinically evaluated to determine the best conditions for transfer to reduce risk to the patient. Users should read and understand the warnings, cautions and notes related to safety, ventilator use, and operation that are contained in the preface of the operator's manuals. Inform all relevant personnel of the information in the Urgent Medical Device Voluntary Field Correction letter, and provide a copy of the letter to any facility to which you have further distributed affected product.
For Further Information:
Covidien technical support department
Tel.: (800) 255-6774 (select option 1, then option 4)
Website: Click here

References:
United States:

- Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 2 recall—Puritan Bennett 700 Series Ventilators (PB740 and PB760) [online]. 2014 Jan 24 [cited 2014 Jan 28]. Available from Internet: Click here.
- Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 2 recall—Puritan Bennett 840 Series Ventilator [online]. 2014 Jan 24 [cited 2014 Jan 28]. 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 Jan 28. FDA CDRH Database. Class II. Z-0822-2014
- 2014 Jan 28. FDA CDRH Database. Class II. Z-0821-2014
- 2014 Jan 28. Member Hospital. Covidien letter submitted by ECRI Institute member hospitals