

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

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Sistema de Ventilación Mecánico PURITAN BENNETT
<b>NO. IDENTIFICACIÓN RISARH</b>	A1410-395
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	PURITAN BENNETT 980
<b>REGISTRO SANITARIO</b>	2008EBC-0001832
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Entregar gases a la vía respiratoria para asistir o suplir las necesidades básicas en condiciones fisiológicas y respiratorias requeridas por el paciente.
<b>NOMBRE DEL FABRICANTE</b>	Covidien Newport Medical Instruments, Inc. Mallinckrodt Medical Covidien Llc
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante informa que durante el normal funcionamiento la interface grafica de usuario (IGU) puede emitir un olor a quemado y volverse opaca, los parámetros y ajustes ventilatorios no se verán afectados pero el equipo debe ser puesto fuera de servicio, lo que puede conllevar a potenciales eventos adversos sobre el paciente.
<b>FUENTE</b>	ANEXO 1
<b>FECHA DE NOTIFICACION</b>	03 de Octubre 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](mailto:tecnovigilancia@invima.gov.co)

## ANEXO 1

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### H0240 - High Priority Medical Device Alert

#### Medical Device Hazard Report

Updated: October 2, 2014

#### UMDNS Terms:

- Ventilators, Intensive Care, Neonatal/Pediatric [14361]
- Ventilators, Intensive Care [17429]

#### Suggested Distribution:

- Pulmonology/Respiratory Therapy
- Critical Care
- NICU
- Clinical/Biomedical Engineering

#### Geographic Regions:

- Worldwide

#### Covidien—Puritan Bennett 980 Ventilators: Graphical User Interface (GUI) May Become Dim if Capacitor Fails

##### Product Identifier:

Covidien Puritan Bennett 980 Ventilators [Capital Equipment]

##### Manufacturer:

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

##### Problem:

During operation, the graphical user interface (GUI) display for the Covidien Puritan Bennett 980 ventilator may emit an electrical burning odor and become dim. Covidien states that ventilation will continue at all previously set parameters and that although the display is dim, machine settings, patient parameters, and alarms are still displayed. During such an event, a substitute ventilator should be employed.

##### Suppliers Corrective Action

Covidien reports that the problem is caused by a capacitor failure on the GUI backlight inverter board. If this occurs, the display illumination will decrease by 50%, but a duplicate circuit is unaffected and continues to power 2 GUI backlights. Covidien will be issuing a customer notification discussing this problem and an unrelated software update in the near future. Covidien plans to issue the notification by October 3rd depending on health authority communications. Covidien also indicated that field service staff will update the 980 ventilators with a new backlight inverter board.

##### ECRI Institute Recommendations:

Until the inverter board is installed, ECRI Institute recommends that users of the above ventilators do the following:

- Ensure that a substitute ventilator is available in the event that the GUI backlight inverter board fails.
- Always have a manual resuscitator available for manual ventilation in the event of a ventilator failure.

##### 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 Oct 1.
- ECRI Institute researched member report.