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	Monitor Multiparametro
NO. IDENTIFICACIÓN RISARH	I1406-235
REFERENCIAS DEL DISPOSITIVO MEDICO	INTELLIVUE X1/X2/MP5/MP5T/MP5SC
REGISTRO SANITARIO	2008EBC-0002562
INDICACIONES Y USO ESTABLECIDOS	Los equipos de monitoreo multiparamétrico son indicados para la monitorización eficaz, registro, medición de los signos vitales y creación de alarmas de numerosos parámetros fisiológicos de pacientes adultos, pediátricos y neonatales. Adicionalmente proporcionan una mayor cantidad de información sin necesidad de alejarse del paciente.
NOMBRE DEL FABRICANTE	Philips Medical Systems Invivo Corporation Philips Medizin Systeme Boeblingen Gmbh Sanmina-Sci Systems Singapore Pte Ltd Shenzhen Goldway Industrial Inc Witt Biomedical Corporation
DESCRIPCION DEL PROBLEMA	El fabricante afirma que en los equipos mencionados anteriormente que cuenten con tecnología de oximetría Nellcor OxyMax pueden presentar un mensaje de error de “mal funcionamiento”, mensaje que en condiciones normales aparecería cuando se conecta un sensor de saturación a un monitor previamente encendido, si se produce este problema el equipo no se podrá restablecer, lo que puede conllevar a un retraso en la atención de los pacientes.
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

S0259 - Normal Priority Medical Device Alert

Medical Device Special Report
Updated: June 5, 2014
UMDNS Terms:
- Monitoring Systems, Physiologic [12636]
- Probes, Pulse Oximeter [17594]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Nursing
- Critical Care

Geographic Regions:
- Worldwide

ECRI Institute User Experience Network—Philips IntelliVue Monitors Using Covidien Nellcor OxiMax Pulse Oximetry May Malfunction

Product Identifier:
(1) Philips Intellivue X1/X2/MP5/MP5T/MP5SC Monitors; (2) Nellcor OxiMax Pulse Oximetry [Capital Equipment]
Manufacturer:
- Covidien RMS (Respiratory & Monitoring Solutions)6135 Gunbarrel Ave, Boulder, CO 80301-3214,
- Philips Medical Systems3000 Minuteman Rd Mailstop 101, Andover, MA 01810,

Problem: The above Philips IntelliVue patient monitors with Nellcor OxiMax pulse oximetry technology may alarm and display a SpO_2 malfunction error message. This problem typically occurs at SpO_2 monitoring initiation if an SpO_2 sensor is plugged into a monitor that is already powered on. If this problem occurs, the SpO_2 cannot be reset and an alternate pulse oximetry monitor will be necessary.

Suppliers Corrective Action

Philips and Covidien have determined that a printed circuit board assembly (PCBA) modification implemented last year caused this error. The firms believe that 0.5-4% of the modules may be affected and the reported failure rate is currently at the low end of this range. Unfortunately, the malfunction is the only means to identify affected units, though a fix is expected within a few weeks.

To minimize the occurrence of this malfunction, the firms recommend the following:

- keep an SpO_2 sensor connected when the monitor is powered on
- minimize the amount of time that the monitor is powered on with no SpO_2 sensor attached
- switch off the monitor when it is not in use

Additionally, Philips and Covidien state this problem does not affect the accuracy of SpO_2 readings. Affected devices will be repaired free of charge when the fix is available.
Covidien has issued a Customer Notification regarding this issue.

ECRI Institute Recommendations:
ECRI Institute recommends the following for users of the above systems:

- Follow the manufacturers' recommendation to keep an SpO_2 sensor connected when the monitor is powered on, minimize the amount of time that the monitor is powered on with no SpO_2 sensor attached, and switch off the monitor when it is not in use.
- If this problem occurs, use an alternate pulse oximetry monitor.

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 Jun 5. ECRI Institute researched member report.
- 2014 Jun 5. Manufacturer. Covidien letter to customers