INFORME DE SEGURIDAD

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 Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Equipos De Monitoreo Multiparamétrico INTELLIVUE y SURESIGNS PHILIPS
NO. IDENTIFICACIÓN RISARH	I1612-583
REFERENCIAS DEL DISPOSITIVO MEDICO	Concernientes a los conectores de referencia específica, usados con los modelos MX40.
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	Witt Biomedical Corporation Philips Medical Systems Invivo Corporation Philips Medizin Systeme Boeblingen Gmbh Sanmina-Sci Systems Singapore Pte Ltd Philips Goldway (Shenzhen) Industrial Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que dado el ajuste entre el paquete de telemetría (MX40) y el conjunto de cables del paciente este es muy ajustado, los usuarios pueden balancear el conjunto de plomo del paciente durante la conexión, cuando esto ocurre el monitoreo fisiológico puede ser intermitente o completamente interrumpido, conllevando a que se presenten posibles eventos adversos serios sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	16 de Diciembre de 2016

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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

[Normal Priority] - S0307 : Philips—MX40 Patient Lead Set Connectors: Dislodged Gasket May Cause Intermittent Physiologic Measurement [ECRI User Experience Network]
Medical Device Special Report

Published: Thursday, December 15, 2016
Last Updated: Friday, December 16, 2016

UMDNS Terms:

- Cables/Leads, Electrocardiography [15754]
- Monitors, Physiologic, Electrocardiography, Telemetric [13988]

Product Identifier:
MX Patient Lead Set Connectors used with MX40 Patient Monitors *[Consumable, Capital Equipment]*
Monitor Model Nos.: 865350, 865351, 865352

0.85 m (35-inch) MX40 Electrocardiograph (ECG) Cables:	Product Nos.:
Adapter Cable	989803172211
Extender Cable	989803172241
Reusable ECG 3-Lead Grabber + SpO_2 IEC Colors	989803171911
Reusable ECG 3-Lead Grabber IEC Colors	989803171901
Reusable ECG 5-Lead Grabber + SpO_2 IEC Colors	989803171951
Reusable ECG 5-Lead Grabber IEC Colors	989803171931
Reusable ECG 6-Lead Grabber + SpO_2 IEC Colors	989803171971
Reusable ECG 6-Lead Grabber IEC Colors	989803171961
Reusable ECG 3-Lead Grabber + SpO_2 AAMI Colors	989803171811
Reusable ECG 3-Lead Grabber + SpO_2 AAMI Colors	989803171871
Reusable ECG 3-Lead Grabber AAMI Colors	989803171801
Reusable ECG 5-Lead Grabber AAMI Colors	989803171831
Reusable ECG 5-Lead Snap + SpO_2 AAMI Colors	989803171841
Reusable ECG 5-Lead Snap AAMI Colors	989803171821
Reusable ECG 6-Lead Grabber AAMI Colors	989803171861
Reusable ECG 6-Lead Grabber + SpO_2 AAMI Colors	989803171851
Single-Patient-Use ECG 5-Lead Grabber + SpO_2 AAMI Colors	989803172051
Single-Patient-Use ECG 5-Lead Grabber + SpO_2 IEC Colors	989803172151

Single-Patient-Use ECG 5-Lead Grabber AAMI Colors	989803172031
Single-Patient-Use ECG 5-Lead Grabber IEC Colors	989803172131

Geographic Regions: Worldwide

Manufacturer(s): Philips Healthcare 3000 Minuteman Rd, Andover, MA 01810, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, Risk Management/Continuous Quality Improvement, Materials Management

Problem:

1. Since the fit between the MX40 telemetry pack and patient lead set is very tight, users may rock the patient lead set onto the MX40 during connection. This can cause the patient lead set connector's internal gasket to dislodge even though externally the connection appears fine.
2. When this occurs, physiologic monitoring may be intermittent or completely interrupted.

    a. Since the dislodged gasket is not apparent, users may waste time troubleshooting.

Manufacturer's Recommendations:

1. Philips Healthcare has issued a service bulletin dated September 1, 2016, discussing proper patient lead set insertion to prevent intermittent physiologic measurements and frequent INOP errors.

ECRI Institute Recommendations:

1. If you receive INOP errors or experience intermittent physiologic measurements while using the MX40, disconnect the patient lead set and verify that the connector's gasket has not dislodged.
    1. If the gasket has become dislodged, change the patient lead set.
    2. Remove affected lead sets from service and return to Philips for replacement.
2. Before use, verify that the connector gasket is not dislodged.
3. Instruct staff to connect the patient lead set to the MX40 as outlined in Philips Service Bulletin.

Background:

- A connector with a dislodged gasket must be replaced.

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):

- 2016 Dec 15. Member Hospital. Philips Service Bulletin submitted by an ECRI Institute member hospital. Reference No. SB86202472A Download