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 Multiparametros ULTRAVIEW SL
NO. IDENTIFICACIÓN RISARH	I1410-398
REFERENCIAS DEL DISPOSITIVO MEDICO	91367, 91369, 91370, 91387 y 91393, seriales específicos.
REGISTRO SANITARIO	2009EBC-0003148
INDICACIONES Y USO ESTABLECIDOS	Indicado para monitoreo de signos vitales en pacientes en estado crítico u observación. Uso en unidades hospitalarias(Uci, Cirugía, Urgencias, etc.) y ambulancias.
NOMBRE DEL FABRICANTE	Spacelabs Medical Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa que la alarma auditiva no sonara si el monitor se deja en modo "*End Case*" sin embargo las alarmas visuales trabajaran normalmente, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	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

ANEXO 1

A16561 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: September 1, 2011
UMDNS Terms:
- Monitoring Systems, Physiologic [12636]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Critical Care
- Emergency/Outpatient Services
- Nursing
- OR/Surgery
- NICU

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- Argentina
- Australia
- Bahrain
- Bolivia
- Brazil
- Canada
- Cayman Island
- Chile
- China
- Colombia
- Cyprus
- Ecuador
- Finland
- France
- Germany
- Guam
- India
- Indonesia
- Israel
- Italy
- Jordan
- Mexico
- Morocco
- New Zealand
- Nicaragua
- Pakistan
- Paraguay
- Peru
- Philippines
- Poland
- Saudi Arabia
- Singapore
- Slovakia
- South Africa
- Spain
- Switzerland
- Syria
- Taiwan
- Thailand
- Trinidad and Tobago
- Turkey
- United Arab Emirates

Spacelabs—Patient Monitors Equipped with Perioperative Option: Alarms May Not Be Audible in End Case

Product Identifier:
Patient Monitors with Perioperative Option (Option D) and Start Case/End Case Functionality:(1) Model 91367, (2) Model 91369, (3) Model 91370, (4) Model 91387, (5) Model 91393 *[Capital Equipment]*
Serial Nos.: For a list of affected serial numbers, see source document.

2,614 units distributed

Manufacturer:
- Spacelabs Healthcare Inc An OSI Systems CoPO Box 7018, Issaquah, WA 98027-7018, United States

Problem: In a July 27, 2011, Urgent Medical Device Correction letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Spacelabs states that the alarm on the above monitors may not sound if the monitor is left in "End Case" mode; however, visual alarms will continue to work normally. FDA's Center for Devices and Radiological Health (CDRH) states that Spacelabs initiated a product correction by Urgent Medical Device Correction letter dated July 25, 2011, and an Updated Recall Notification letter dated July 27, 2011. The manufacturer has not confirmed the information provided in the source material.

Regulatory Agency:	Designation:
FDA	Class II Recall No. Z-3032-2011
Health Canada	Type II Recall No. 66067
MHRA	2011/008/010/291/015
BfArM	Reference No. 3656/11

Action Needed: If you have affected product, verify that you have received the July 27, 2011, Urgent Medical Device Correction letter from Spacelabs. Identify any affected product in your inventory. Clinicians should familiarize themselves with the "Start Case/End Case" feature described in the perioperative section of the operations manual. Spacelabs is developing a software upgrade to improve the visibility of the audio alarm status. A Spacelabs representative will contact your facility when the upgrade becomes available. Inform all relevant personnel at your facility of the information in the Urgent Medical Device Correction letter.

For Further Information:

Geographic Location:	Contact:	Telephone No.:	Website:
U.S.	Spacelabs technical support department	(800) 522-7052 (select option 2)	Click here
Outside the U.S.		(425) 657-7200, ext. 5089	

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- Uruguay
- U.S.
- Venezuela

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.

Verification History: Action Announced by FDA [8/22/2011 9:48:22 AM]; Action Announced by Non-U.S. Regulatory Agency [8/22/2011 2:15:09 PM]

Source:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical & radiation emitting device recalls: Class 2 recall—Spacelabs medical patient monitor [online]. 2011 Aug 17 [cited 2011 Aug 22]. Available from Internet: Click here.

- Germany. Federal Institute for Drugs and Medical Devices. Safety notice for Ultraview SL 2200, 2400, 2600, 2700 and XPREZZON monitors with perioperativ-option *[sic]*, Spacelabs Medical [online]. 2011 Aug 19 [cited 2011 Aug 22]. Available from Internet: Click here.

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Monitors, patient multiparameter monitor. Spacelabs Medical patient monitor - 91367, 91369, 91370, 91387 and 91393. [online]. London: Department of Health; 2011 Aug 30 [cited 2011 Aug 30]. (Field safety notice; reference no. 2011/008/010/291/015). Available from Internet: Click here.

- Health Canada. Medical device recall listings [online]. 2011 Sep 19 [cited 2011 Sep 21]. Available from Internet: Click here.

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