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	Sistema de Perfusión Modular SARNS 8000
NO. IDENTIFICACIÓN RISARH	I1703-93
REFERENCIAS DEL DISPOSITIVO MEDICO	Concerniente a los *pads* y gel referencias 195240 y 217390, lotes 782300 hasta 817488.
REGISTRO SANITARIO	2012EBC-0000781-R1
INDICACIONES Y USO ESTABLECIDOS	Maquina corazón /pulmón de 4 a 5 módulos en donde se pueden acomodar bombas modulares de sangre. Es una maquina completa para cirugía cardiotorácica, este sistema básico incluye un monitor de seguridad para la detección de burbujas de aire, el monitor recibe energía de la línea de parada y transmite señales a la base.
NOMBRE DEL FABRICANTE	Terumo Cardiovascular Systems Corporation
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos médicos referenciados podrán mostrar en su etiqueta una fecha de caducidad en un formato que es irreconocible para el usuario, si un usuario no puede reconocer correctamente la fecha de caducidad y utiliza un producto vencido, la adherencia del sensor puede no ser correcta y llevar a una inadecuada interfaz, lo cual podría conllevar a que se presenten retrasos en la atención de los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	13 de Marzo de 2017

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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] - A28148 : Terumo—Level Sensor II Pads and Gel: Expiration Date Format on Label May Be Unrecognizable to User
Medical Device Ongoing Action

Published: Friday, February 24, 2017
Last Updated: Monday, March 20, 2017

UMDNS Terms:

- Heart-Lung Bypass Units [11969]
- Pumps, Extracorporeal Perfusion [13203]

Product Identifier:
Level Sensor II Gel and Level Sensor II Pads used with the following Heart-Lung Machines: (1) Sarns System 8000, (2) Terumo System 1 *[Consumable, Capital Equipment]*

Level Sensor II Products:	Catalog Nos.:	Lot Nos.:
Gel	217390	782300 through 817488
Pads, 60 Pack	195240	782300 through 817488

Pad and Gel units distributed between November 23, 2015, and December 15, 2016

Geographic Regions: Australia, Belgium, Canada, Chili, China, Colombia, Costa Rica, Dubai, India, Indonesia, Japan, Kuwait, Malaysia, Mexico, Nicaragua, Panama, Singapore, South Africa, Taiwan, Thailand, Uruguay, U.S., Vietnam

Manufacturer(s): Terumo Cardiovascular Systems Corp6200 Jackson Rd, Ann Arbor, MI 48103, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, OR/Surgery, Perfusion, Materials Management

Problem:
In a February 20, 2017, Urgent Safety Advisory letter submitted by ECRI Institute member hospitals, Terumo states that the expiration date on the label of the above pads and gel products may be displayed in a format that is unrecognizable to the user. If a user is unable to properly recognize the expiration date and uses an expired product, the sensor pad may not properly adhere or hold the sensor in place on the reservoir. Expired gel may result in inadequate interface of the sensor to the reservoir. Terumo also states that this problem may be detected during connection and testing of Level Sensor pads and Level Sensors at the time of setup because of warnings provided by the heart-lung machine. If attachment problems appear after setup, such as during a case, the system response will be:

- Terumo System 1: The condition is detected and reported to the user with a "Not Attached" message, without affecting the pump.
- Sarns System 8000: The condition is presented to the user the same as a low level condition. See the Operator's Manual for complete user instructions.

Terumo further states that this problem was identified during an internal investigation and that the firm has received no reports of illnesses or injuries related to this problem.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the February 20, 2017, Urgent Safety Advisory letter and Customer Response Form from Terumo. Terumo states that it is not requesting removal or return of affected product. The firm is providing directions on how to read the expiration date on affected product labels. The earliest expiration date for affected product is July 7, 2017, which appears on the labels as "(17)170707." The earliest expiration date for affected product is July 7, 2017, which appears on the labels as "(17)170707," where "(17)" indicates the code for the expiration date, 17 indicates the year, 07 the month, and 07 the day. Terumo recommends that users confirm the expiration date for affected product and use affected product before that date. For examples of expiration date formatting and location on the labels, see the letter . Notify all relevant personnel at your facility of the information in the letter. Complete the Customer Response Form, and return it to Terumo using the instructions on the form. Insert the addenda at the beginning of the appropriate sections of the Operators Manual. U.S. customers should report serious adverse events or product quality problems relating to the use of affected product to FDA's MedWatch Adverse Event Reporting program by telephone at (800) 332-1088 or online at the MedWatch website .
For Further Information
Terumo customer service department
Tel.: (800) 521-2818, 8 a.m. to 6 p.m. Eastern time, Monday through Friday,
Website: Click here

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):

- 2017 Feb 22. Member Hospital. Terumo letter submitted by ECRI Institute member hospital (includes reply form). Terumo reference no. AA-2017-001-SA Download