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	Enfriador / Calentador de Depósito Dual HEMOTHERM - TERUMO
NO. IDENTIFICACIÓN RISARH	I1704-127
REFERENCIAS DEL DISPOSITIVO MEDICO	HEMOTHERM 400CE, seriales 151-10283CE hasta 171-10721CE, fabricados entre 01 de enero de 2015 y 06 de febrero de 2017.
REGISTRO SANITARIO	2010DM-0005283
INDICACIONES Y USO ESTABLECIDOS	Es utilizado ya sea para bajar o subir la temperatura de la sangre y/o para mantener la temperatura de la sangre, como se requiera, por medio de transferencia conductiva de calor.
NOMBRE DEL FABRICANTE	Cincinnati Sub-Zero Products, Inc Terumo Latin America Corporation
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos médicos referenciados podrán tener sus fusibles indebidamente clasificados en las tarjetas de alimentación, lo cual producirá retrasos hasta interrupción de la terapia, conllevando a que se presenten eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	03 de Abril de 2017

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO 1

[High Priority] - A28290 : Cincinnati Sub-Zero—Hemotherm CE 115 V Heater-Cooler Units: Improperly Rated Power Board Fuses May Result in Interrupted or Delayed Therapy

Medical Device Ongoing Action

Published: Thursday, March 23, 2017
Last Updated: Monday, April 3, 2017

UMDNS Terms:

- Warming/Cooling Units, Patient, Circulating-Liquid [12074]

Product Identifier:
Hemotherm CE 115 V Heater-Cooler Units *[Capital Equipment]*
Model No. 400CE; Serial Nos. 151-10283CE through 171-10721CE
Units manufactured between January 1, 2015, and February 6, 2017

Geographic Regions: Colombia, Mexico, Taiwan, U.S.

Manufacturer(s): Cincinnati Sub-Zero Products LLC12011 Mosteller Rd, Cincinnati, OH 45241-1528, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Nursing, OR/Surgery, Perfusion

Problem: In a March 9, 2017, Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, Cincinnati Sub-Zero (CSZ) states that improperly rated fuses on the power boards of the above heater-cooler systems may result in interrupted or delayed therapy.

Action Needed:
Identify, isolate, and discontinue use of any affected systems in your inventory. If you have affected systems, verify that you have received the March 9, 2017, Urgent Medical Device Correction letter, Response Form, 2 replacement fuses, and service kit installation procedure instructions from CSZ. Remove and discard the 2 affected fuses and replace them with the new fuses from CSZ according to the service kit installation procedure instructions. Complete the Response Form, and return it to CSZ using the instructions on the form. Inform all relevant personnel at your facility of the information in the Urgent Field Safety Notice letter, and provide a copy of the letter to any facility to which you have distributed affected product.
For Further Information:
Kathy DeSmidt, CSZ field action coordinator
Tel.: (513) 772-8810 or (800) 989-7373
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 Mar 22. Member Hospital. March 9, 2017 Cincinnati Sub-Zero letter submitted by ECRI Institute member hospital (includes reply form) Download
- 2017 Mar 23. Manufacturer. Manufacturer confirmed information.