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	Maquinas para Diálisis BAXTER
NO. IDENTIFICACIÓN RISARH	I1707-300
REFERENCIAS DEL DISPOSITIVO MEDICO	HomeChoice y HomeChoice PRO
REGISTRO SANITARIO	2008EBC-0002066
INDICACIONES Y USO ESTABLECIDOS	Para efectuar diálisis peritoneal
NOMBRE DEL FABRICANTE	Baxter Healthcare S.A. Baxter Healthcare Corporation
DESCRIPCION DEL PROBLEMA	El fabricante ha identificado que los usuarios no siguen las instrucciones del manual del operador que indican que se debe abrir manualmente el envase desechable y no usar herramientas que puedan dañar las láminas del casete, tales como cuchillos, tijeras y accesorios de sujeción, si el usuario no sigue estas instrucciones para abrir el envase desechable, la válvula de paciente en la lámina del casete puede dañarse y el daño podría pasar sin ser detectado por el equipo y por el usuario, conllevando a que se presenten potenciales eventos adversos sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	17 de Julio de 2017

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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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

[High Priority] - A28934 : Baxter—HomeChoice and HomeChoice PRO Automated PD Cyclers: Failure to Adhere to Disposable Set Opening Instructions May Cause Cassette Damage, Potentially Leading to Delivery of Air into Patient Line
Medical Device Ongoing Action

Published: Wednesday, July 12, 2017

UMDNS Terms:

- Peritoneal Dialysis Units [11226]

Product Identifier:

115 V Automated Peritoneal Dialysis (PD) Cyclers:	Product Nos.:
HomeChoice	5C4471
HomeChoice Serviced	5C4471R
HomeChoice PRO	5C8310
HomeChoice PRO Serviced	5C8310R

[Capital Equipment]
All serial numbers

Geographic Regions: Worldwide

Manufacturer(s): Baxter Healthcare CorpOne Baxter Pkwy, Deerfield, IL 60015-4625, United States

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Dialysis/Nephrology, Nursing, Home Care

Problem:
In a July 5, 2017, Important Product Information letter submitted by an ECRI Institute member hospital, Baxter states that it has been made aware that users may not be following the instructions in the operator's manual of the above cyclers and may be incorrectly opening the disposable set packaging while setting up PD therapy, potentially damaging the cassettes for the cyclers. Baxter also states that the operator's manual specifically instructs the operator to open the disposable set packaging by hand and not to use tools that may damage the cassette sheeting, such as knives, scissors, and clamp accessories. If the user does not follow these instructions for opening the disposable set packaging, the patient valve portion of the cassette sheeting (see Figure 1 in the letter) may be damaged and the damage may go undetected by the cycler and the user. If this occurs, delivery of air into the patient line at a rate of 10 to 30 mL/minute may result during the fill or dwell phase of PD therapy. Baxter further states that this may result in pneumoperitoneum (air in the peritoneal cavity), which, if clinically significant, would present as pain. With increased intraperitoneal pressure from significant volume of air, there is potential for serious adverse health consequences.

Action Needed:
As instructed in the operator's manual and the patient at-home guide, open the packaging of disposable sets by hand. Do not use a knife, scissors, or other sharp object to open the packaging. Be aware that flow of fluid out of the connector at the end of the patient line after the prime phase of PD therapy is a visual indication of the potential for air delivery because of an undetected hole over the patient valve area in the cassette sheeting. Baxter is updating the HomeChoice labeling to include the additional risk information described above, including the following excerpt:

- "NOTE: Fluid flow out of the connector at the end of the patient line when only the heater bag is on the heater pan and when the patient line or extension line is correctly positioned in the organizer may indicate a hole in the cassette sheeting and could lead to delivery of non-sterile air to your peritoneal cavity.
- "End therapy. Return the disposable set to Baxter by calling Baxter Technical Assistance at the number located in Numbers to Call for Assistance on page 1-1. Restart your therapy using all new supplies (solution bags and disposable set)."

For the complete new labeling, see the enclosure in the letter . If you received the Customer Reply Form directly from Baxter, complete and return it to Baxter using the instructions on the form. If you did not receive a letter and reply form directly from Baxter, do not return a reply form to Baxter. Notify all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed affected product. Report any adverse events associated with the use of affected product to the Baxter Corporate Product Surveillance department by telephone at (800) 437-5176, from 8 a.m. to 5 p.m. Central time, Monday through Friday, or by e-mail at corporate_product_complaints_round_lake@baxter.com (click here). U.S. customers should also 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; fax at (800) 332-0178; by mail (using postage-paid FDA form 3500, available here) at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website .

For Further Information:
For clinical inquiries:
Baxter renal clinical helpline
Tel.: (888) 736-2543 (select option 2), 8 a.m. to 4:30 p.m. Central time, Monday through Friday
For general inquiries:
Baxter product surveillance department
Tel.: (800) 437-5176, 8 a.m. to 5 p.m. Central time, Monday through Friday
Website: Click here

Comments:

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

- 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 Jul 12. Member Hospital. Baxter letter submitted by an ECRI Institute member hospital: FA-2017-017 Download
- 2017 Jul 12. Manufacturer. Baxter confirmed the information provided in the source material.