

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	Máquina para Diálisis
NO. IDENTIFICACIÓN RISARH	I1411-474
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 Corporation Baxter Healthcare S.A.
DESCRIPCION DEL PROBLEMA	El fabricante informa que se encuentra realizando la actualización de las advertencias y precauciones adicionales en el etiquetado de los productos referenciados como 5C4471, 5C4471R, 5C4474, 5C8310, 5C8310R, R5C8320, T5C4441 y T5C8300, dichas consideraciones podrían afectar la seguridad de los pacientes, conllevando a que se presenten potencialmente eventos adversos serios sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	21 de Noviembre 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

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A23176 01 - High Priority Medical Device Alert

**Medical Device
Ongoing Action**

Updated: November 13,
2014

UMDNS Terms:

- Peritoneal Dialysis
Units [11226]

Suggested Distribution:

- Clinical/Biomedical
Engineering
- Critical Care
- Dialysis/Nephrology
- Home Care
- Nursing

Geographic Regions:

- Africa
- Asia
- Canada
- Europe
- Latin America
- Middle East
- U.K.
- U.S.

***Baxter—HomeChoice and HomeChoice PRO Automated
Peritoneal Dialysis Systems: Manufacturer Implements
Additional and Updated Warnings and Cautions Labeling
[Update]**

Product Identifier:

Automated Peritoneal Dialysis (PD) Systems: (1) HomeChoice, (2) HomeChoice
PRO [Capital Equipment]

Product Nos.: 5C4471, 5C4471R, 5C4474, 5C8310, 5C8310R, R5C8320, T5C4441,
T5C8300

Manufacturer:

- Baxter Healthcare Corp 1 Baxter Pkwy, Deerfield, IL 60015-4625, United States

Summary:

This Alert provides additional information based on a November 2014 Important
Product Information letter posted by the U.K. Medicines and Healthcare Products
Regulatory Agency (MHRA) and an Important Product Information letter provided by
the manufacturer regarding [Alert Accession No. A23176](#). Additional information is
provided in the following fields:

- Product Identifier (see bolded information)
- Geographic Regions (see bolded region)

Problem:

[October 15, 2014]

In an October 6, 2014, Important Product Information letter submitted by an ECRI
Institute member hospital, Baxter states that it is implementing additional and updated
warnings and cautions regarding various topics in the labeling of the above systems.
Baxter also states that the additional and updated warnings and cautions could affect
the safety of a patient or third party. Baxter further states that it has not received an
increase in the number of reports of adverse events associated with the use of the
above systems.

Action Needed:

The following actions are those listed in [Alert Accession No. A23176](#). Identify any
affected product in your inventory. If you have affected product, verify that you have
received the Important Product Information letter, Customer Reply Form, and copy of
the additional and updated warnings and cautions from Baxter. Review the additional
and updated warnings and cautions in the [Important Product Information 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, it is not necessary to return a reply form to Baxter. Report
any adverse events associated with the use of affected product to Baxter using the
information in the letter. 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; by fax at (800)
332-0178; by mail (using postage-paid FDA form 3500, available [here](#)) or online at
the MedWatch [website](#).

For Further Information:

U.K.:

Surecall Baxter Medical Information

Tel.: (01635) 206345

E-mail: surecall@baxter.com

U.S.:

For clinical questions:

Baxter renal clinical helpline

Tel.: (888) 736-2543 (select option 2), 8 a.m. to 5 p.m. Central time, Monday through

Friday

For general questions:

Center for One Baxter

Tel.: (800) 422-9837, 8 a.m. to 5 p.m. Central time, Monday through Friday

Outside U.K. and U.S.:

Baxter local representative

Website: [Click here](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Baxter Healthcare. Dialysis, peritoneal. All HomeChoice automated PD system and HomeChoice PRO automated PD system [online]. London: Department of Health; 2014 Nov 10 [cited 2014 Nov 11]. (Field safety notice; reference no. 2014/011/005/121/009). Available from Internet: [Click here](#).

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](#).

Source(s):

- 2014 Nov 11. MHRA FSN. 2014/011/005/121/009
- 2014 Nov 11. MHRA FSN. November 2014 Baxter letter posted by MHRA: FCA-2014-035
- 2014 Nov 12. Manufacturer Letter. Baxter letter provided by the manufacturer: FCA-2014-035
- 2014 Nov 12. Member Hospital. October 6, 2014, Baxter letter submitted by an ECRI Institute member hospital: FCA-2014-035
- 2014 Nov 12. Manufacturer. Baxter confirmed the information provided in the source material.