

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	Equipo Automatizado para Análisis Inmunoquímicos
NO. IDENTIFICACIÓN RISARH	I1409-372
REFERENCIAS DEL DISPOSITIVO MEDICO	600, 800, UniCel DxC, DxC 660i, DxC 680i, DxC 860i, 880i
REGISTRO SANITARIO	2010DM-0005321
INDICACIONES Y USO ESTABLECIDOS	Equipo automatizado para hacer análisis Inmunoquímicos IN VITRO en laboratorio clínico.
NOMBRE DEL FABRICANTE	Beckman Coulter Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que si los sistemas antes mencionados son de reciente fabricación y/o recientemente han sido revisados, pueden contener una muestra no conforme de los cables pertenecientes a las sondas de prueba, lo que puede provocar un retraso en informar los resultados; causar errores de los sentidos de nivel e impedir el inicio de las pruebas o su cancelación de forma automática, lo que puede conllevar a que se presenten potencialmente retrasos en la atención a los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	19 de Septiembre 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

www.ecri.org • Printed from Health Devices Alerts on Friday, September 19, 2014 Page 1

A22998 - Normal Priority Medical Device Alert

**Medical Device
Ongoing Action**

Updated: September 16, 2014

UMDNS Terms:

- Analyzers, Laboratory, Clinical Chemistry/Immunoassay [20821]

Suggested Distribution:

- Clinical/Biomedical Engineering
- Clinical Laboratory/Pathology

Geographic Regions:

- Canada
- China
- Colombia
- Croatia
- Czech Republic
- France
- Germany
- India
- Italy
- Japan
- Korea
- Kuwait
- Malaysia
- Mexico
- Philippines
- Puerto Rico
- Russia
- Singapore
- Slovakia
- South Africa
- Spain
- Sweden
- Switzerland
- Taiwan
- Thailand
- Turkey
- U.K.
- U.S.
- Vietnam

Beckman Coulter—UniCel DxI Access Immunoassay Systems and UniCel DxC Synchron Access Clinical Systems: Nonconforming Sample Probe Cables May Have Been Installed

Product Identifier:

UniCel DxI Access Immunoassay Systems: (1) 600, (2) 800, and UniCel DxC Synchron Access Clinical Systems: (3) DxC 660i, (4) DxC 680i, (5) DxC 860i, (6) 880i [Capital Equipment]

Manufacturer:

- Beckman Coulter (UK) Ltd Oakley Court Kingsmead Business Park, High Wycombe HP11 1JU, England

Problem:

In an August 29, 2014, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Beckman Coulter states that if the above systems are newly manufactured and/or have recently been serviced, they may contain nonconforming sample probe cables. Beckman Coulter also states that use of a nonconforming sample probe cable may cause a delay in reporting results; however, this will not cause erroneous results. Beckman Coulter further states that a nonconforming sample probe may also cause level sense errors, which may prevent tests from starting or automatically cancel an in-process test.

Action Needed:

Identify any affected instruments in your inventory. Only newly manufactured instruments shipped from Beckman Coulter between May 22 and August 8, 2014, or instruments serviced during the same time period, are potentially affected by this problem. If you have affected instruments, verify that you have received the August 29, 2014, Urgent Field Safety Notice letter and Response Form from Beckman Coulter. Beckman Coulter states that you may continue to operate affected instruments normally and that your Beckman Coulter service representative will contact your facility to schedule a service visit to ensure that a conforming sample probe cable is installed on your system(s). Complete the Response Form, and return it to Beckman Coulter using the instructions on the form. Retain a copy of the Urgent Field Safety Notice letter as part of your laboratory Quality System documentation, 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.

For Further Information:

Beckman Coulter local representative or Beckman Coulter customer support hotline
Tel.: (0845) 6001345
E-mail: techsupportuk@beckman.com
Website: [Click here](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Beckman Coulter. IVDs, clinical chemistry assay kit immunoassay. Sample probe cable—for use with the UniCel DxI family of immunoassay systems [online]. London: Department of Health; 2014 Sep 8 [cited 2014 Sep 9]. (Field safety notice; reference no. 2014/008/029/601/003). 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 Sep 9. MHRA FSN. 2014/008/029/601/003
- 2014 Sep 9. MHRA FSN. FSN 23515
- 2014 Sep 16. Manufacturer. Beckman Coulter confirmed the information provided in the source material.