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	Analizador de Inmunología BECKMAN COULTER
NO. IDENTIFICACIÓN RISARH	I1801-51
REFERENCIAS DEL DISPOSITIVO MEDICO	ACCESS 2, UniCel DxC 600i SYNCHRON, seriales específicos.
REGISTRO SANITARIO	2017DM-0017033 2010DM-0005517
INDICACIONES Y USO ESTABLECIDOS	Equipo biomédico de diagnóstico in vitro que se utiliza para la determinación cuantitativa, semicuantitativa o cualitativa de varias concentraciones de analito que se encuentran en líquidos corporales humanos.
NOMBRE DEL FABRICANTE	Beckman Coulter Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa que pueden ocurrir quemaduras leves en la piel si la herramienta entra en contacto con la placa de interfaz de almacenamiento de reactivo (B78817) cuando se realiza una alineación de la pipeta en los sistemas anteriores, lo anterior podría conllevar a que se presenten retrasos y eventos adversos sobre los usuarios.
FUENTE	ANEXO
FECHA DE NOTIFICACION	23 de enero de 2018

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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

Accession Number: A29801 **High Priority** Published: Thursday, January 11, 2018

Beckman Coulter—Access 2 and UniCel DxC 600i SYNCHRON Access Clinical Systems: Skin Burn May Occur if Tool Contacts Reagent Storage Interface Board When Pipettor Alignment Is Performed

UMDNS Device Term(s):

Analyzers, Laboratory, Clinical Chemistry [15551];

Product Identifier:

Collapse identifier information

[Capital Equipment]

Product	Beckman Coulter Inc Model	Catalog No.	Serial No.
Immunoassay Systems	Access 2	81600N	570005, 570006, 570007, 570008, 570009, 570010, 570011, 570012, 570013, 570014, 570015, 570016, 570017, 570018, 570019, 570020, 570021, 570022, 570023, 570024, 570025, 570026, 570027, 570028, 570029, 570030, 570031, 570032, 570033, 570034, 570035, 570036, 570037, 570038, 570039, 570040, 570041, 570042, 570043, 570047, 570048, 570049, 570051, 570052, 570053, 570054, 570055, 570056, 570057, 570058, 570059, 570060, 570061, 570066, 570067, 570068, 570069, 570070, 570071, 570073, 570074, 570075, 570076, 570077, 570078, 570079, 570080, 570081, 570082, 570083, 570084, 570085, 570086, 570087, 570088, 570089, 570090, 570091, 570093, 570094, 570095, 570096, 570097, 570098, 570099, 570100, 570101, 570102, 570103, 570104, 570105, 570106, 570107, 570108, 570109, 570110, 570111, 570112, 570113, 570114, 570115, 570116, 570117, 570118, 570119, 570120, 570121, 570122, 570123, 570125, 570126, 570128, 570131, 570132, 570133, 570134, 570135, 570136, 570137, 570138, 570139, 570140, 570141, 570142, 570143, 570144, 570145, 570146, 570147, 570148, 570149, 570150, 570151, 570152, 570153, 570156, 570157, 570158, 570159, 570160, 570161, 570162, 570163, 570164, 570165, 570166, 570167, 570168, 570169, 570170, 570171, 570172, 570173, 570174, 570175, 570176, 570177, 570178, 570179, 570180, 570181, 570182, 570183, 570184, 570185, 570186, 570187, 570188, 570189, 570190, 570191, 570192, 570193, 570194, 570195, 570196, 570197, 570198, 570199, 570200, 570201, 570202, 570203, 570205, 570206, 570207, 570208, 570209, 570210, 570211, 570212, 570213, 570214, 570215, 570216, 570217,

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			570218, 570219, 570220, 570221, 570222, 570223, 570224, 570225, 570226, 570227, 570228, 570229, 570230, 570231, 570232, 570233, 570234, 570235, 570236, 570237, 570238, 570239, 570240, 570241, 570244, 570245, 570246, 570247, 570248, 570250, 570251, 570252, 512684
	Access 2 (Remanufactured)	386220	507114, 503299, 508111
	UniCel DxC 600i SYNCHRON Access Clinical	A25638, A25656	801060, 801061

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Argentina, Canada, Chile, China, Colombia, Costa Rica, France, Georgia, Germany, Ghana, Greece, Hong Kong, India, Italy, Japan, Kazakhstan, Mexico, Morocco, Myanmar, Nepal, Philippines, Poland, Russia, Rwanda, Saudi Arabia, Slovakia, South Africa, South Korea, Thailand, Turkey, U.K., U.S., Vietnam

Manufacturer(s): Beckman Coulter Inc [362269], 250 S Kraemer Blvd, Brea, CA 92821-6232, United States

Problem:

FDA's Center for Devices and Radiological Health (CDRH) states that minor skin burns may occur if the tool contacts the reagent storage interface board (B78817) when a pipettor alignment is performed on the above systems. FDA's CDRH also states that the manufacturer initiated a recall by Urgent Medical Device Recall letter dated November 6, 2017. The manufacturer has not confirmed the information provided in the source material.

Action Needed:

Identify any affected systems in your inventory. If you have affected systems, verify that you have received the November 6, 2017, Urgent Medical Device Recall letter from Beckman Coulter. Beckman Coulter states that you may continue to operate affected systems normally. If a device on the instrument needs alignment, contact the Beckman Coulter technical support department. The alignment tool is to be used only by Beckman Coulter service personnel and Beckman Coulter trained biomedical engineers. A Beckman Coulter service representative will contact your facility to schedule a service visit. Notify all relevant personnel at your facility of the information in the letter, and retain a copy of the letter with your records. Respond to Beckman Coulter using the instructions in the letter.

For Further Information:

Beckman Coulter

Website: Click here

References:

United States:

- Food and Drug Administration. Center for Devices and Radiological Health. Class 3 device recall Access 2 immunoassay system [online]. 2018 Jan 3 [cited 2018 Jan 10]. Available from Internet: Click here.
- Food and Drug Administration. Center for Devices and Radiological Health. Class 3 device recall Access 2 immunoassay system [online]. 2018 Jan 3 [cited 2018 Jan 10]. Available from Internet: Click here.
- Food and Drug Administration. Center for Devices and Radiological Health. Class 3 device recall Access 2 immunoassay system [online]. 2018 Jan 3 [cited 2018 Jan 10]. 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.

Suggested Distribution: Clinical Laboratory/Pathology, Clinical/Biomedical Engineering