

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	Procesador de Tejidos LEICA
NO. IDENTIFICACIÓN RISARH	I1508-409
REFERENCIAS DEL DISPOSITIVO MEDICO	ASP6025
REGISTRO SANITARIO	2014DM-0012120
INDICACIONES Y USO ESTABLECIDOS	Solo el personal calificado debe utilizar el procesador de tejidos. El equipo ha sido diseñado de tal modo que funciona a prueba de fallos - tanto en lo que se refiere al usuario, como a las muestras a procesar - siempre que el usuario cumpla en todo momento con las instrucciones del manual de usuario. El equipo ha sido diseñado para las siguientes aplicaciones en laboratorio: fijación, deshidratación, infiltración en parafina de muestras histológicas.
NOMBRE DEL FABRICANTE	Leica Biosystems Nussloch GmbH
DESCRIPCION DEL PROBLEMA	El fabricante que el sistema de detección de nivel puede de forma incorrecta reportar una condición de "botella vacía" durante el llenado, antes de completar el llenado de 5 L, conllevando a que se presenten potencialmente fallos en los resultados de análisis de las muestras y poder requerir repetir las biopsias.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	21 de Agosto de 2015

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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[High Priority] - A24899 : Leica—Model ASP6025 Tissue Processors: May Incorrectly Detect "Bottle Empty" Condition during Retort Filling Medical Device Ongoing Action

Published: Wednesday, August 12, 2015
Last Updated: Wednesday, August 19, 2015

UMDNS Terms:

- Tissue Processors [15190]

Product Identifier:

Model ASP6025 Tissue Processors [Capital Equipment]

Geographic Regions: Worldwide

Manufacturer(s): Leica Biosystems Nussloch GmbH Heidelberger Strasse 17-19, D-69226 Nussloch, Germany

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

Problem:

In a July 29, 2015, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Leica states that the above tissue processors may incorrectly detect a "bottle empty" condition during retort filling after passing fill level sensor 2 and before reaching fill level sensor 3, before completing 5 L filling. Leica further states that this problem could lead to suboptimal processing and may necessitate re-biopsy of the patient.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the July 29, 2015, Urgent Field Safety Notice letter and Return Response Form from Leica. Leica states that users should not use the 3 baskets (5 L) mode; instead, use the 2 baskets (3.8 L) mode. To set the processor to the 2 baskets (3.8 L) mode, do the following:

1. In the graphical user interface (GUI), go to "Menu."
2. Select the "Enhancement" option.
3. Open the "System Setup" submenu.
4. Change the basket mode to "2 baskets (3.8L)." The retort filling volume will now be 3.8 L, allowing for a maximum of 2 baskets to be processed per processing run.
5. To optimize performance, fill reagent bottles to 3.8 L instead of 5 L.

Complete the Return Response Form, and return it to Leica using the instructions on the form. Notify all relevant personnel at your facility of the information in the Urgent Field Safety Notice letter, and forward a copy of the letter to any facility to which you have further distributed product.

For Further Information:

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Website: [Click here](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Leica Biosystems: ASP6025 tissue processor [online]. London: Department of Health; 2015 Aug 10 [cited 2015 Aug 11]. (Field safety notice; reference no. 2015/008/004/291/001). Available from Internet: [Click here](#).
- Germany. Federal Institute for Drugs and Medical Devices. Corrective action for the Leica ASP6025 tissue processor, Leica Biosystems Nussloch GmbH [online]. 2015 Aug 19 [cited 2015 Aug 19]. Available from Internet: [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):

- 2015 Aug 11. MHRA FSN. 2015/008/004/291/001 [Download](#)
- 2015 Aug 11. MHRA FSN. (includes reply form) [Download](#)
- 2015 Aug 11. Manufacturer. The manufacturer confirmed the information in the source material and provided additional details.
- 2015 Aug 19. BfArM (Germany). 4929/15 [Download](#)
- 2015 Aug 19. BfArM (Germany). (includes reply form) [Download](#)

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