

Urgent Field Safety Notice for ASP6025

Attention: Lab Manager, User of the ASP6025

29/07/2015

Dear Sir/Madam,

Leica Biosystems is issuing this Urgent Field Safety Notice (FSN) to inform you about a Field Safety Corrective Action (FSCA) that we are initiating, to address an issue we have experienced with our tissue processor, ASP6025. You have received this notification as our records indicate that you have received one or more of the instruments concerned.

Details on affected devices:

All ASP6025, Tissue Processor

Description of the problem:

The ASP6025 is sporadically and incorrectly getting into the wrong instrument state "bottle empty" during retort filling, after passing fill level sensor 2 and prior to reaching level sensor 3, thus prior to completing the 5 litre filling. This potentially leads to suboptimal quality of processed tissue. In some cases, a re-biopsy of the patient could be necessary in order to obtain another viable tissue sample.

Advice on immediate actions to be taken:

As an immediate countermeasure please do not use the "3 baskets (5l)" mode; instead please use the "2 baskets (3.8l)" mode for processing of up to two baskets only.

Instruction for properly setting the "2 baskets (3.8l) mode":

Via GUI (Graphical User Interface) on the instrument go to 'Menu' and select the 'ENHANCEMENT' option. Open the sub menu 'SYSTEM SETUP' and change 'BASKET MODE' to "2 baskets (3.8l)".

The filling volume of the retort is now 3.8 litres, allowing you to process a maximum of two baskets per processing run. This setting change should remain in effect only, until further notification is issued from Leica Biosystems.

To optimize the performance of the instrument, please fill up the reagents bottles with 3.8litres instead of 5litres.

Your prompt understanding and assistance is appreciated and necessary to prevent possible loss of patient tissue. Please note that all efforts are being enacted at Leica Biosystems to correct this issue as soon as possible.

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Transmission of this Field Safety Notice:

This Field Safety Notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness of this Field Safety Notice and resulting action to ensure effectiveness of the corrective action.

Contact reference person:

Should you have any questions, please contact

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Please sign the enclosed Urgent Field Safety Notice Response form to confirm that you have received and understood this Field Safety Notice.

We are sincerely sorry for any inconvenience caused by this issue.

Best regards,



Frederik Nitschke

Quality Manager

Leica Biosystems Nussloch GmbH

(The undersign confirms that the FSN is being made with the knowledge of the relevant Health Authorities)

URGENT FIELD SAFETY NOTICE RETURN RESPONSE FORM
ASP6025, Tissue Processor

Please record the serial number of your device(s):

Please check both boxes.

I have read and understood the Field Safety Notice.

Name: _____

Title: _____

Phone: _____

Firm Name: _____

Address: _____

City/State: _____

Signature: _____

Please fax completed response form within 5 days after receipt to 0049/(0)6224 143 5337

Or mail to: Leica Biosystems Nussloch GmbH
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Heidelberger Str. 17-19
69226 Nussloch – Germany
Frederik.Nitschke@leicabiosystems.com